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OVERSIGHT AND BUSINESS PRACTICES OF DURABLE MEDICAL EQUIPMENT COMPANIES

HEARING

BEFORE THE

SUBCOMMITTEE ON FINANCIAL AND CONTRACTING OVERSIGHT

OF THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

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OVERSIGHT AND BUSINESS PRACTICES OF DURABLE MEDICAL EQUIPMENT COMPANIES

WEDNESDAY, APRIL 24, 2013

U.S. SENATE,
SUBCOMMITTEE ON FINANCIAL AND CONTRACTING OVERSIGHT,
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:04 a.m., in room 342, Dirksen Senate Office Building, Hon. Claire McCaskill, Chairman of the Subcommittee, presiding.

Present: Senators McCaskill, Baldwin, and Johnson.

OPENING STATEMENT OF SENATOR MCCASKILL

Senator MCCASKILL. The hearing will come to order.

This is the first hearing of the Subcommittee on Financial and Contracting Oversight (FCO). I know that both Senator Johnson and I are glad to have the opportunity to serve in this regard and I know I can speak for him in this way, that we both want to figure out ways that the government behaves better with taxpayer dollars, and that is what this Subcommittee is all about. We will work very hard to be responsible and fair, but at the same time be very aggressive about finding ways that the government can save money in the way they spend hard-earned taxpayers' dollars.

This charter of this Subcommittee is to ensure that money is spent wisely and effectively, and we will continue to conduct investigations and hold hearings that will help fight and end some of the waste and some of the fraud in both government and the private sector that contracts with the Federal Government.

We are not interested in making life difficult for companies that do not enjoy profit as a result of their work on behalf of the Federal Government. But if you work for the Federal Government, the Federal Government has the right to demand standards and to demand accountability, because, ultimately, you are, in fact, enjoying taxpayer funding.

Today's hearing will focus on how the Centers for Medicare and Medicaid (CMS) pay businesses who supply durable medical equipment (DME), such as diabetic testing materials, machines that assist with sleep apnea, back braces, and power wheelchairs to Medicare beneficiaries under Medicare Part B. The hearing will also examine how these medical equipment suppliers market and promote these products to patients and their doctors.

Medicare is a vital safety net for the elderly and the medical equipment provided to beneficiaries at a low cost to them can improve their quality of life and prevent costly visits to clinics and hospitals. Unfortunately, loopholes in the law and inadequate oversight may be allowing some companies to exploit Medicare for their personal gain.

Most Americans have seen ads on TV or received calls or letters promising medical equipment at little or no cost to you. What is never made fully clear in these materials is that there is always a cost to you because it is taxpayer dollars. The products provided will be billed to Medicare and ultimately will be paid for by the American people.

Last year, the Federal Government spent nearly $9 billion on payments for medical equipment under Medicare Part B, and we are not even sure about that figure. CMS estimates that as much as 66 percent of this, almost $6 billion, may have been improperly paid to companies who submitted claims for equipment that was not medically necessary, was not properly justified, or was never even delivered.

One significant concern is that the prevalent practice among some medical equipment companies is that they aggressively call, e-mail, and write Medicare beneficiaries to directly market their products. I first learned of this practice from Dr. Charlotte Kennedy of Chesterfield, Missouri, who wrote to me about companies who were calling her patients to badger them into asking for medical supplies. Dr. Kennedy has been besieged by faxes from companies asking her to sign prescriptions for these patients so that the companies can bill Medicare.

After I heard from Dr. Kennedy, I reached out to my constituents to find out if they had experienced similar problems. In less than 2 weeks, I had more than 150 replies. Among them is Victoria Anderson, who lives with her 87-year-old mother, Carol Hughes, in Southwest Missouri. Ms. Anderson and her mother get as many as three to four calls from medical marketing companies every single day. They are on the Federal Trade Commission's (FTC) "Do Not Call List" and have repeatedly told companies they are not interested in their products and have asked to have their names removed from all company call lists. But the calls have not stopped. Ms. Anderson told us that she and her mother would report these companies, but they cannot figure out their names. When they ask the telemarketers to identify the companies they are working for, the people on the other end of the line refuse to give them a straight answer.

Medicare prohibits these type of phone calls unless the patient has given their prior written consent or the company has provided medical equipment to the patient previously. In fact, some of these companies may be using tactics which are unfair, deceptive, or illegal.

What is clear to me is that the law, as written, does not appear to be working as intended to address the problems that I am hearing about from my constituents. Today, I intend to ask questions of CMS officials and one of the contractors responsible for program integrity about what tools the government has to crack down on these sorts of schemes and abuses. I also intend to ask how the

government, taxpayers, or Medicare beneficiaries are served by permitting durable medical equipment companies to aggressively market their products to patients who do not need or want them until they are told they can have them for free or almost free, and I put that "free" in quotes.

I will also ask CMS why it is failing to identify and recover improper payments to these suppliers. In 2011, the most recent year for which this information has been provided, CMS recovered less than 1 percent of the over $5 billion, with a "B", in improper payments that the CMS has identified as having gone out to durable medical equipment suppliers. That is unacceptable.

We have invited representatives of two durable medical equipment companies mentioned by Dr. Kennedy, Med-Care Medical and Diabetes Supply and U.S. Healthcare Supply, to provide testimony today about their companies' business practices. Sample reviews by CMS of these companies, which together have received almost $140 million from Medicare in the last 4 years, show a very high error rate and denial rates for durable medical equipment. The Subcommittee staff has prepared a memorandum outlining the information received by the Subcommittee, and at this time, I ask unanimous consent that this memorandum be included in the hearing record.

I also ask for unanimous consent that the information provided by Dr. Kennedy[1] about these two companies be included in the hearing record.

The Subcommittee invited Jon Letko, the head of U.S. Healthcare Supply, and Dr. Steve Silverman of Med-Care Diabetic and Medical Supplies, to testify at today's hearing. After receiving the Subcommittee's invitation to testify, both individuals, through their attorney, have declined to appear voluntarily before the Subcommittee today. I continue to believe that these companies can provide us useful information that would assist the Subcommittee in its oversight, and we will continue to discuss the possibility of these witnesses appearing in front of us at a future date.

Keep in mind, these companies are profitable for one reason, and that is the American taxpayer. I look forward to the opportunity to talk with our witnesses today about what is needed to ensure that we do not continue to throw billions of dollars a year down the drain.

I would like to take the opportunity to welcome Senator Johnson, the Ranking Member for the new Subcommittee on Financial and Contracting Oversight. I want to take this opportunity to publicly thank Senator Johnson and his staff for their cooperation and support during this hearing. I know that both of us share a desire to work in a bipartisan way, effectively and fairly, to try to recover money on behalf of the American taxpayer. This has been a genuinely bipartisan process and I am very grateful for their efforts and I continue to look forward to working with them as we get at these problems in every area of the Federal Government.

I am also very grateful to Dr. Kennedy. There are many Americans who write letters to their Senators. There are many Americans that do not believe that their Senators pay much attention.

[1] Information provided by Dr. Kennedy appears in the Appendix on page 87.

I want to thank Dr. Kennedy for believing in her government and believing that if she brought this to our attention, something would happen.

All the people who have helped the Subcommittee in this investigation have been very supportive, but I especially want to thank Dr. Kennedy and Ms. Anderson, my constituent who also pointed out the problems that she had dealing with this issue and her mother.

I thank the witnesses for being here and I look forward to their testimony. Senator Johnson

OPENING STATEMENT OF SENATOR JOHNSON

Senator JOHNSON. Thank you, Madam Chairman, and really, thank you for delving into this issue here and holding this hearing.

I agree with you that fraud and abuse of the system is costly to taxpayers and I am looking forward to working with you on an ongoing basis to continue to hold hearings like this to try and get some control over these systems, over some of these government programs. And as we were talking earlier, that is a real challenge.

I think we all share the same goal. We want an effective and efficient government, and the trick is—I come from the private sector, and we were talking about earlier that in the private sector, you have the fiscal discipline of going bankrupt, of making sure that you not only just balance your budget, but have a surplus. You have to make a profit. And in government, as these programs grow, it is how do you institute the controls so that you have bad actors that take advantage of it. How do you prevent that going forward? It is a very difficult issue.

But I think it might be interesting to just give a little history lesson on the expansion of the Medicare program and how we have such a difficult time controlling its cost. Both Medicare and Medicaid were basically set up in the mid-1960s. When they initially estimated how much Medicare would cost the American taxpayer, they projected about 25 years and they said that Medicare would cost $12 billion in the year 1990. In fact, it ended up costing $110 billion, nine times the original estimate.

So the first thing you have to understand is government is not particularly good at estimating the future cost of some of these programs. Today, when you combine Medicare and Medicaid in terms of outlays from CMS, it is a little over $765 billion, which represents about 21 percent of our entire Federal budget and about 27 percent of the $2.8 trillion that we spend on health care every year.

The program, in terms of number of Americans it serves, when you combine both of them, when they first started, they served about 29 million Americans. Today, they serve 107 million Americans, about 35 percent of our population. So these are huge programs. Thirty-five percent of our population take advantage or are beneficiaries of the programs, so these are important programs and we need to make sure that they run efficiently, effectively, and they do not waste taxpayer dollars and that they are not abused by the suppliers of the system.

In getting prepared for this hearing, you quoted some of these statistics, but I want to just kind of go back over the dollars spent on durable medical equipment—about $10 billion a year. I am

rounding these figures. And the improper payment of that in 2011 was 61 percent, which is $5.9 billion. Now, you have to think about that. I come from the private sector. If 61 percent of our expenditures were made improperly or paid to fraudulent suppliers, We would not be in business, and yet that has been going on in Medicare probably for years.

And then as you mentioned, Madam Chairman, the amount that we recovered out of that year was $34 million, about 0.6 percent of the improper payments. So I have some real questions in terms of how could that be. I mean, what is really the improper payment? Is it a technical violation in terms of paperwork or what? I mean, we really have to get our arms around that.

I will conclude here quickly, but I just want to talk about the bureaucracy involved in Medicare, and I think that might be part of the problem, is Medicare contracts with a number of outside suppliers and it is a real alphabet soup of agencies. You have your Community Emergency Response Teams (CERTs). You have your National Supplier Clearinghouse (NSC), your Medicare Administrative Contractors (MACs), your Zone Program Integrity Contractors (ZPICs), your Receovery Audit Contractors (RACs), all these independent contractors are making payments and auditing, and it is obviously not working very well.

And when you take a look—and one of the people testifying in the second panel lists the different types of frauds, and right now, she lists six of them. I just want to quickly list them. Telemarketing fraud scheme. You have your services not provided fraud scheme. You have items not medically necessary fraud scheme. No relationship with ordering physician fraud scheme. False-front suppliers. And this is one of my favorite, provision of DME while patient is under hospice care, residing in a skilled nursing facility fraud scheme.

Now, again, we are dealing with an important government program that is just set up that can be preyed upon this way. And certainly as we were researching this, so many of these fraud schemes are perpetrated by individuals that set up shop, commit the fraud, and by the time the government is aware of them, they have already got their millions. They have left town.

So, again, I really appreciate the fact that you are holding this hearing. I think it is extremely important for us to get to the bottom of these things and I am really looking forward to questioning particularly the witnesses from Medicare and CMS so I can try and get my arms around what is the problem here.

Thank you, Madam Chairman.

Senator MCCASKILL. Thank you, Senator Johnson.

We also welcome Senator Baldwin. We are pleased that you have come to the hearing this morning. I hope you come often. We will always try to make these lively and interesting. And I can say with authority after 6 years, not every hearing is in the Senate. So I hope that you will make this a regular stop for your schedule, because we will try very hard to make sure every hearing is cutting edge.

If I could, at this time, we will proceed. Since our witnesses have not appeared that we have invited that are medical equipment suppliers, we will proceed with testimony from our second panel of wit-

nesses, if you would come to the table and we will introduce you. While you are sitting, if you do not mind, I will go ahead with the introductions so that we can proceed.

Peter Budetti is Deputy Administrator for Program Integrity of the Centers for Medicare and Medicaid Services and Director of the CMS Center for Program Integrity. He has principal responsibility for program integrity policies and operations in the Medicare and Medicaid programs. Before joining CMS, Dr. Budetti worked in health care positions in government and the private sector. He holds a medical degree from Columbia University and a law degree from Boalt Hall at the University of California in Berkeley.

Laurence D. Wilson is the Director of the Chronic Care Policy Group in the Centers for Medicare and Medicaid Services, the CMS Center for Medicare, where he has responsibility for policy on a broad range of fee-for-service (FFS) health care benefits, including post-acute care, home health, hospice, durable medical equipment, dialysis, and various hospital services. Mr. Wilson has worked for CMS since 1988, where he directed the design and implementation of a number of key Medicare reforms, including the establishment of prospective payment systems for inpatient rehabilitation facilities, skilled nursing facilities, and other health care services, and the competitive bidding program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Mr. Wilson holds a Master's degree in public administration from Pennsylvania State University.

Charlene Stanley is the ZPIC Operations Director for AdvanceMed. She has oversight for ZPIC Zones 2 and 3, and tell me what the acronym is for ZPIC.

Ms. STANLEY. Zone Program Integrity Contractor. It is actually Zones 2 and 5.

Senator MCCASKILL. OK, it is 2 and 5. I did not say it? It is written 2 and 5. I misspoke. Say it again, because I do not want to say ZPIC anymore.

Ms. STANLEY. That is OK. Zone Program Integrity Contractor.

Senator MCCASKILL. Zone Program Integrity Contractor. She has oversight of both Zone Program Integrity Contractor Zones 2 and 5. She is a registered nurse and has worked in various clinical areas, including the emergency response and hospice settings earlier in her career. She also holds a Master of Business Administration (MBA) from Franklin University.

Thank you all for being here. It is the custom of this Subcommittee to swear all witnesses that appear before us, so if you do not mind, I would ask you to stand.

Do you swear that the testimony that you will give before the Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. BUDETTI. I do.

Mr. WILSON. I do.

Ms. STANLEY. I do.

Senator MCCASKILL. Let the record reflect the witnesses have answered in the affirmative.

We will be using a timing system today. We would ask that you try to hold your testimony to no more than 5 minutes. If you go slightly over, we will be understanding. Obviously, your entire

written testimony will be part of our record, and we will begin with you, Dr. Budetti.

TESTIMONY OF PETER BUDETTI,[1] M.D., DEPUTY ADMINISTRATOR AND DIRECTOR, CENTER FOR PROGRAM INTEGRITY, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Dr. BUDETTI. Thank you, and good morning, Chairman McCaskill, Ranking Member Johnson and Senator Baldwin. Thank you for this invitation to discuss the initiatives that we are taking at the Centers for Medicare Medicaid Services to deal with what we agree is a plague that has been with the DME program for some time now that involved a serious amount of fraud, waste, and abuse, as well as other forms of improper payments. So I am happy to be here to discuss our various initiatives to overcome those problems.

With me is my colleague from CMS, Laurence Wilson, who will speak about one of the major initiatives that is being implemented to address this from a different perspective than simply fighting fraud, and that is our competitive bidding program, and so you will hear about that, as well. And you will also hear about the way that our private sector contractors, our investigative contractors, the Zone Program Integrity Contractors work with us as partners in fighting fraud, as well.

I would like to focus on our initiatives to root out the bad actors who manage to get into the program and to keep them from getting into the program, and I would like to point out that we have had a series of initiatives in recent years that have had a degree of success in reducing the overall threat to the program from suppliers who should not be in the program, should not be billing us. This is an important aspect.

One of the many tools that we are using along these lines is the structure that was set up by the Affordable Care Act under which we are implementing risk-based screening of new applicants and re-validation of existing suppliers. According to the requirements of the Affordable Care Act, we put all providers and suppliers into three categories of limited, moderate, or high-risk of fraud and abuse.

New DME suppliers, we put into the high-risk category, and existing DME suppliers into the moderate risk category. All applicants and all current providers and suppliers are subject to background checks and licensure and other kinds of certification. The ones in the moderate category also get site visits, and we have, in fact, conducted some 86,000 site visits over the last couple of years, and the newly enrolling DME suppliers will also be subject to criminal background checks through the Federal Bureau of Investigation (FBI) and fingerprinting after we work out the terms of the arrangements for doing that.

To date, due to our site visits and other controls on the new applicants, we have denied 430 DME applications because the entity was simply not operational. It just did not exist. And as part of our re-validation efforts, as well, we have since March 2011 deactivated

[1] The prepared statement of Mr. Budetti appears in the Appendix on page 57.

nearly 25,000 DME enrollments and revoked over 1,700 DME supplier enrollments.

That work, the enrollment and screening of DME suppliers, is the work of one dedicated contractor, and that is the National Supplier Clearinghouse that you referenced earlier, Senator Johnson, and that I will be delighted to talk about. But they do the background checks. They conduct the unannounced site visits. They make sure that the suppliers meet all of the Federal requirements.

I also want to mention a major new initiative that we have underway, the Fraud Prevention System (FPS). We have been using highly sophisticated new tools to screen the pattern of claims that we are getting, as opposed to simply looking at one claim at a time, under the Fraud Prevention System, and we have been working very closely with our private sector colleagues, as well, on this. We have implemented a very sophisticated system that uses advanced analytics to identify problems and patterns, and I will be happy to answer more questions about that as we go on.

And I would also like to emphasize that we continue to have and we continue to expand our collaboration with our law enforcement colleagues. We are working even closer than ever with our law enforcement colleagues. In fact, we have FBI agents and Office of Inspector General (OIG) staff now embedded with us in our headquarters at the Center for Program Integrity (CPI) on a regular basis. And that, of course, has been a very successful collaboration under the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative that has operated in the context of the strike forces around the country.

So I am pleased to highlight the activities that we have done so far. I look forward to working with the Subcommittee and the Congress to continue our progress in modernizing the way that we pay for and oversee the very important durable medical equipment benefit for Medicare beneficiaries, and I thank you for this opportunity.

Senator MCCASKILL. Thank you very much, Dr. Budetti. Mr. Wilson.

TESTIMONY OF LAURENCE D. WILSON,[1] DIRECTOR, CHRONIC CARE POLICY GROUP, CENTER FOR MEDICARE, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. WILSON. Good morning, Chairman McCaskill, Ranking Member Johnson, and Senator Baldwin. I am very pleased to be here today to discuss an important payment reform CMS is implementing in the area of durable medical equipment, prosthetics, orthotics, and supplies.

The competitive bidding program required under the Medicare Modernization Act (MMA) of 2003 has already been effective in reducing beneficiary out-of-pocket costs, improving the accuracy of Medicare's payments, reducing overutilization, and ensuring beneficiary access to high-quality items and services. Lower, more accurate prices and other safeguards included in the program support CMS's overall efforts to address fraud, waste, and abuse in this important area.

[1] The prepared statement of Mr. Wilson appears in the Appendix on page 57.

CMS successfully implemented the program on January 1, 2011, in nine large metropolitan areas after making a number of important improvements based on new requirements from Congress and after working closely with stakeholders. The program has already saved in excess of $200 million in each of its first 2 years of operation with no disruption in access or negative health consequences for our beneficiaries. We are now poised to expand the program to 91 additional areas of the country, including some of the largest, like New York, Los Angeles, Chicago, on July 1, as the law requires.

Competitive bidding brings value to Medicare beneficiaries and taxpayers compared to the current fee schedule required by law. The average price discount across the initial nine areas was 35 percent. For the additional 91 areas, this discount climbs to 45 percent. The CMS Actuary projects that the program will save $25.7 billion for Medicare over the next 10 years and save an additional $17.1 billion for beneficiaries through lower co-insurance and premiums.

A few examples I would share with you. In St. Louis, Missouri, the payment amount for a standard power wheelchair drops $2,034. That is a savings for Medicare of $1,627 and for the beneficiary of $407.

Likewise, in Milwaukee, the payment amount for a powered mattress dropped $4,147. That is a savings for Medicare and the taxpayers of $3,318 and for the beneficiary of $829.

The program also applies important safeguards, including quality standards, accreditation, financial standards, an active monitoring program, and enhanced oversight to protect beneficiaries and Medicare while supporting good quality. CMS has worked to implement the competitive bidding program in a way that is fair for suppliers and sensitive to the care needs of beneficiaries.

For example, the program includes provisions to promote small supplier participation and numerous protections for beneficiaries to ensure they get the services they need. The program results in a large number of winners so that beneficiaries are ensured access and choice and that there will continue to be competition among contract suppliers on the basis of customer service and quality.

We have continued to make improvements to the program to ensure a fair process that is less complex for suppliers to navigate and results in more effective scrutiny of suppliers' qualifications and the integrity of their bids.

In addition, to help fulfill our commitment to ensure effective oversight and quality and access for our beneficiaries, we have put in place a comprehensive monitoring system which examines 100 percent of Medicare claims and other data, complaint data. We have observed no trends in health status indicators or access to care that cause concern. We have seen problem areas associated with overutilization, such as diabetes testing supplies, drop dramatically.

We are very pleased with the success of round one of the program. We will continue to be diligent and thoughtful in our implementation of this important program as it expands to additional areas of the country. We will continue to monitor the implementa-

tion closely and be open to further improvements suggested by our stakeholders, Members of Congress, and others.

In summary, by ensuring that Medicare pays accurately through competitively determined prices, we can provide better value to Medicare, to taxpayers, and beneficiaries. By eliminating excessive payments under the current fee schedule and paying the right price, we can also reduce incentives for fraud, waste, and abuse in the program.

Again, I very much appreciate the invitation to testify before you today and we would be happy to take any questions at the close of testimony.

Senator MCCASKILL. Thank you, Mr. Wilson. Ms. Stanley.

TESTIMONY OF CHARLENE STANLEY,[1] ZONE PROGRAM INTEGRITY CONTRACTOR OPERATIONS DIRECTOR, ADVANCEMED CORPORATION

Ms. STANLEY. Chairman McCaskill, Ranking Member Johnson, Senator Baldwin, thank you for the request to attend this hearing today to share with you our efforts to prevent, identify, and address fraud and abuse in the Medicare program, especially as it relates to durable medical equipment.

As a Zone Program Integrity Contractor to CMS, we have a responsibility to note only protect the Medicare Trust Fund, but also to protect beneficiaries, providers, suppliers, and taxpayers from fraud, waste, and abuse. CMS awarded the umbrella to the Indefinite Delivery Indefinite Quantity (IDIQ) contract to ZPIC Zone 5 to AdvanceMed in February 2009 and the IDIQ contract for Zone 2 in September 2009.

As a Zone Program Integrity Contractor, AdvanceMed conducts fraud, waste, and abuse detection and investigation in 10 States as ZPIC Zone 5 and 14 States as ZPIC Zone 2. We also have seven fully operational Medicare-Medicaid data matching projects in the two zones.

The fundamental activities of ZPICs are those that help ensure payments are appropriate and consistent with Medicare and Medicaid coverage, coding, and audit policy, and are aimed at identifying, preventing, and/or correcting potential fraud, waste, and abuse.

I would like to give the Subcommittee a few examples of the kind of program integrity issues that we have identified within the durable medical equipment, prosthetics, orthotics, and supplies Medicare benefit.

The first issue that I know the Subcommittee has an interest in is telemarketing to Medicare beneficiaries. As Chairman McCaskill mentioned in her opening remarks, DME suppliers are prohibited from soliciting the beneficiaries unless the beneficiary has given written permission to the supplier to make contact by telephone, the contact is regarding a covered item that the supplier has already furnished to the beneficiary, or the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months.

[1] The prepared statement of Ms. Stanley appears in the Appendix on page 73.

In our investigations of beneficiary complaints about telemarketing, we have discovered that suspect DME suppliers may question Medicare beneficiaries about whether or not they have common medical complaints or symptoms, such as an example would be back or neck pain, and then attempt to have a back or neck brace or other equipment shipped to the beneficiary without proper medical evaluation or order. Subsequently, of course, the item is billed to Medicare and paid.

Telemarketing scams by suppliers have also become more sophisticated, with the sharing of beneficiary identifying information, such as beneficiary Health Insurance Claim (HIC) numbers, between suppliers and clearinghouses, and these are used to make mass calls. Companies many times will offer free items, such as cookbooks, glucometers, other items, in an attempt to get beneficiaries to provide their identifying information.

As a part of CMS's efforts to identify and resolve complaints more efficiently, effectively, and timely, AdvanceMed has been contracted to conduct a pilot project that involves receiving, reviewing, and resolving complaints that are received by the 1–800–MEDICARE program. The Zone 5 Beneficiary Complaint Pilot Project receives information regarding telemarketing and other issues from beneficiaries alleging that they have been contacted by DME companies or their subcontractors promising medical equipment at little or no charge to them, as Chairman McCaskill mentioned earlier, as well.

When AdvanceMed receives these complaints, beneficiaries are interviewed by staff and subsequently asked to sign an attestation affirming that the contact was made without their consent and that the beneficiary does not want nor need the offered item. AdvanceMed then places an auto-deny edit in the claims processing system to prevent the suspect supplier from billing unnecessary equipment to the beneficiary. The beneficiary's Health Insurance Claim number is also added to the National Compromised Data base for further tracking and analysis. Additionally, they are sent an education letter, warning letter, about the telemarketing practice and the matter is referred to the National Supplier Clearinghouse that Dr. Budetti mentioned earlier for review and consideration of revocation and practices.

Another issue that we have noted in both zones is that patients are receiving excessive amounts of glucose strips, which are used by diabetics to test their blood sugars. In October 2011, Zone 2 conducted proactive data analysis to review beneficiaries receiving excessive amounts of glucose strips. Although it is not uncommon for patients to require blood sugar testing multiple times per day, the amounts were well beyond policy limits. Subsequent analysis and beneficiary interviews showed that multiple DME suppliers were selling glucose test strips and other diabetic supplies to the same beneficiaries at the same time. It was also discovered that some DME suppliers were making unwanted and unsolicited marketing phone calls to beneficiaries for glucose strips and DME supplies.

As Senator Johnson mentioned in his opening statement, and I will briefly go through these, the other trends that we are seeing in our investigations in suspect DME suppliers and supplies are for services not provided or services not medically necessary. In some

cases, the supplier has an arrangement with a physician to approve orders for equipment, prosthetics, orthotics, or supplies, even though the physician has no prior relationship with that patient and never having assessed them for the need for such supplies. Typically, the physicians are paid on a fee-for-service basis based on the volume of orders they sign.

Another issue that runs across the supplier types is the false-front providers, again, that Senator Johnson mentioned. In this scheme, a supplier number is established for a DME supplier that does not exist. There is no physical location for the supplier nor do they possess the appropriate equipment to deliver to Medicare beneficiaries. The supplier subsequently obtains Medicare beneficiary numbers, and through identity theft or purchasing them directly from the beneficiaries, bills for the supplies that are never delivered. These providers may work alone or with others to steal the identity of valid Medicare providers and then submit false claims directing.

A final program issue is—that we have noted in a number of investigations—supplies being billed to Medicare when another entity has already paid for the service that includes DMS supplies, for instance, the Medicare beneficiary being under hospice care or skilled nursing facility and the equipment or supplies necessary for the treatment of the diagnosis relating to that admission often covered under the hospice benefit or within the payment to the skilled nursing facility. In this situation, that supplier, who may be affiliated with the hospice, unbundles the equipment and bills them separately to Medicare.

This concludes my remarks on the efforts of the Zone Program Integrity Contractor for Zones 2 and 5 to identify, prevent, and address fraud, waste, and abuse in the Medicare program. I appreciate this Subcommittee's interest in protecting Medicare beneficiaries and taxpayers and thank you again for inviting me to present to this Subcommittee.

As a nurse by trade, this is a topic that is near and dear to my heart. More detailed information is within my written testimony, and I look forward to answering any questions you may have.

Senator MCCASKILL. Thank you all for your testimony.

I am going to begin with some of the misleading and abusive tactics. I am going to ask to be included in the record letters that we received from someone who responded to our tweet asking people to let us know when they had been slammed or pressured by these marketers, and we got these letters from a woman, and we have redacted her personal information, but the letter says, "Welcome to our sleep apnea supply program. Congratulations and welcome. Based on your conversation with one of our intake professionals, your sleep apnea supply prescriptions have been sent to the following physician," and it has her doctor's name on the letter. When we receive your prescription, we will contact you, and then so forth.

And then, basically, the interesting part of the second page of the letter is that it gives her the option of only opting out by calling. The only way that she can opt for a purchase or a rental, is by calling these people.

And then she got a followup letter saying, "We have been unable to reach you," and with her doctor's name in bold. "We need a call today so we can get you your requested supplies."

Now, the interesting thing about this is this woman said, when she got the phone call, guess who she thought it was? The name is Med-Care. So she assumed Medicare was calling her.

So my first question to all of you is, why would you let a company name itself Med-Care? I mean, that is asking for trouble, right?

Dr. BUDETTI. I do not believe that we have the authority to control the choice of names by individual suppliers in the country. There may be some things that do violate Federal rules, but I am not aware that we have that authority, Senator.

Senator MCCASKILL. Well, I think that is something we need to look into. So if a company came and said, we want to be a provider of medical equipment and we want to call ourselves Medicare——

Dr. BUDETTI. I think there are limits. I think that there are some limits, but I am not aware of what those are.

Senator MCCASKILL. Well, if verbally it sounds the same, because, obviously, Med-underscore-Care on paper does not look like Medicare, but if the rules are such—and as you all know, the rule is you have to have permission in order to start doing this. So in order to get permission, this company decided they would obviously use a name that would heighten the likelihood that a senior getting the call saying, "This is Med-Care and we have something for you," I guarantee you, my mom, if somebody called and said they were Med-Care, she would assume that it was Medicare.

So I would appreciate followup on that, if you all have the authority to—when a name is so similar that it is verbally going to be identical for purposes of marketing to Medicare, whether you have the authority to do that.

Why should we not stop companies from doing this entirely? Why should not this be the doctor that is providing these prescriptions rather than having this middleman that is trying to work both ends of the stick, trying to entice the patients to think that their doctor wants it and trying to entice the doctors to think that their patient wants it, and meanwhile, nobody wants it but the one who is making the buck in the middle?

Dr. BUDETTI. The order and the certification that the patient needs the durable medical equipment does have to come from an appropriate certified health care professional, most often, of course, physicians, in a lot of cases. And that is the order for it. And then the supply has to come from the supplier. There are some physicians who also serve as durable medical equipment suppliers in certain subspecialties, but generally, that is not the case. Generally, there is a separate process for the provision of the durable medical equipment to the beneficiary on the physician's order and on the certification that there has been a face-to-face, as required by the physician.

So we have a process, of course, for assuring that the correct physicians are enrolled properly to be able to order the supplies and then we have a process for overseeing the suppliers of the medical equipment themselves and to make sure that they meet standards. So it is a continuum, much as it is going to the drug

store and having a prescription filled by a pharmacy for a pharmaceutical.

Mr. WILSON. Chairman McCaskill, if I may just add to that——

Senator MCCASKILL. Sure.

Mr. WILSON. Thank you. One of the reasons these kinds of companies engage in these type of schemes is because the items that they are supplying are so profitable under the Medicare fee schedule. So the fee schedule is set in law. It is based on charges from the early 1980s that have been updated over time. It does not represent the true market cost of the items. That is what we are paying.

So to the extent that they are hugely profitable, that attracts them to generate revenues. If we can bring the price down, like we can in competitive bidding, we can get a 47 percent discount. I think the discount for round two for the Continuous Positive Airway Pressure (CPAP) devices, which I think this mentions, is about 47 percent. That takes away that windfall profit and makes companies less likely to engage in providing stuff that people do not need.

Senator MCCASKILL. I agree with you, and I do think the competitive bidding program is going to save our country a lot of money.

By the way, if you do the math on our debt and deficit, you come to the inescapable conclusion that the debt and deficit is health care. So all the talk we have around this building, if you actually get into the numbers, you realize that it is health care costs that are driving the debt and deficit. And if we can reduce health care costs by 10 percent meaningfully, by 10 percent, we do amazing things to both our deficit and our long-term debt curve.

Let me ask you this. Are you worried with the competitive bidding, if we take the mass profit out, then these suppliers—it is going to have to be volume, because they are not going to be able to make big money on each individual—they are going to have to sell a lot more of it. Are we prepared for a transition from a business model to see if you can worm your way into the doctor's office or the patient's home to how can we do mass marketing in a way that we can catch more fish because we are not going to make as much off each whale, the same kind of money as we have been making off the big whales?

Mr. WILSON. Right. That is a very good question, Chairman McCaskill. When we implemented round one of the program in nine large areas of the country, including Miami, Riverside, Pittsburgh, a number of others, we did not see that. We saw actually utilization come down. We saw access maintained and health outcomes maintained. And we got over $200 million in savings in two successive years.

So we did not see that type of attempt to increase utilization. In fact, by having a smaller number of contract suppliers that are accredited, that meet financial standards, including looking at credit scores, looking at their tax records, having more effective oversight, we were able to ensure that services were provided, that program integrity was a key focus, and, again, that was not a result that we saw.

Senator MCCASKILL. And this is my last question and I want to move on to my colleagues, but why do we not require this prescription to be on the doctor's letterhead?

Mr. WILSON. I will defer to my colleague on that.

Dr. BUDETTI. So, the physician has to do the ordering of the supply, and that is one of the links in the chain that we are very conscious of. And, in fact, we published two years ago—an updated regulation that establishes the requirements for being able to order and refer in the Medicare program. It is one thing if the physician is seeing the patient and submitting a bill. Then we have a bill to track back to that physician. But if the physician is writing an order, then we have to have a process for making sure that the supplier knows that the physician who is ordering that supply is, in fact, credentialed, if you will, by the Medicare program to be able to order supplies——

Senator MCCASKILL. But, Dr. Budetti, my point is that they are—some doctors are signing 400, 500 of these at once and they are getting these forms that are all done for them by the company that is moving the equipment. This is not being generated by the doctor. This is being checked off by the doctor. Why are we not requiring that the document be generated by the doctor with the appropriate information about the supplier and let the doctor decide what supplier to use and figure out what supplier to use? But it is clear from the documents we got that these documents are being prepared by the supplier, not by the doctor.

Dr. BUDETTI. So, as I said, the control should be—and the ordering should all be in the hands of the physician. And so when we see patterns that look like the ones that you have described, that is exactly the kind of pattern that our new much more sophisticated system for looking at the kinds of bills that we are getting and the patterns of the billing that we are getting allows us now to spot and to take action on. And I think that is exactly one of the concerns that we have, is that this should not be generated—it should be generated by the patient's need and the patient's need should be reflected by the physician. And then the supplier should supply the durable medical equipment that the patient actually needs and that the physician has certified, and that is the——

Senator MCCASKILL. I do not know that—and I do not want to cut you off, but I am over my time.

Dr. BUDETTI. Sure.

Senator MCCASKILL. I do not know that I have a great answer about why we cannot require the doctor to generate the form, but we will move on. Senator Johnson.

Senator JOHNSON. Thank you, Madam Chairman.

I have 30 years in manufacturing, so it is just in my DNA to try and get to the root cause, which may be difficult here.

Mr. Wilson, I appreciate the competitive, whatever you call it, your competitive model, bidding model, but you mentioned something about the fee schedule, that Congress sets the fee schedule. I guess maybe the first lesson learned here is Congress is not particularly good or efficient at price fixing.

So let us talk about why we would encumber ourselves with a fee schedule that, I think, Dr. Budetti, according to your testimony, saddles Medicare with paying three to four times the market price.

Now, that should not be a very difficult thing to fix when you take a look at—especially with the Internet now, you can really get a competitive price very quickly. Why are we not changing the fee schedule, and maybe is that not the first thing we ought to do here, is go to Congress to get them to give you flexibility in the fee schedule?

Mr. WILSON. Well, I think there are a few things I would say about that, sir. The fee schedule was set at a point in time when the Medicare program was just paying charges submitted by suppliers. Whatever you wanted to put on your claim in terms of charges, we would pay it.

Senator JOHNSON. It is totally outdated now.

Mr. WILSON. Yes, and so——

Senator JOHNSON. And so why do we not change it?

Mr. WILSON. We fixed that based on changes in the law to put a fee schedule in place. That became distorted over time, and there are a number of different OIG and the Government Accountability Office (GAO) reports pointing to excessive prices paid under the fee schedule for wheelchairs and negative pressure wound therapy devices and other things, diabetic testing supplies.

But then Congress, in its wisdom, put in place the competitive bidding program, and that is what we have been using to try to drive down prices to a more reasonable, appropriate level. Congress also, in its wisdom, allows us, once we have put these initial set of prices in place under competitive bidding, to use that information and establish a new fee schedule.

Senator JOHNSON. But would it not just be easier to just do away with the fee schedule and do something more competitive, I mean, on a case-by-case basis?

Mr. WILSON. Well, I think one of the problems in this area, Senator Johnson, is that there is a lack of data on what a true market price is. So in order to——

Senator JOHNSON. No, there is a plethora of data out there. You have the Internet now. This is easy to do, to actually figure out what is a fair price to pay for any product nowadays. It has never been easier. It is incredibly simple.

Mr. WILSON. You can certainly find data on the Internet, and we certainly have looked at that in the past. I would say that the type of discounts we are getting by going to suppliers and asking them to bid actually provide better value to Medicare than some of the prices we find on the Internet.

Senator JOHNSON. OK. I appreciate the numbers that you were throwing out, $27.5 billion saved estimated over the next 10 years, but that is $2.7 billion divided by more than $700 billion. That is 0.35 percent. It is better than nothing, but it is not much better than nothing.

I want to go through the whole payment process here, because I do not understand it. CMS, Medicare, contracts out to Medicare Administrative Contractors, four of them, to actually make the payments, and then also, apparently, determine whether the payment they have made is improper. I mean, describe that to me.

Dr. BUDETTI. So, there is a long history of interaction with the private sector in the Medicare program, and, in general, it is helpful to think about our contractors in certain functions. There are

contractors who do, in fact, handle the money, pay the claims, and have initial responsibility for overseeing whether those claims are valid under the Medicare rules and whether they should be paid, and there is opportunity to stop the payment in that circumstance.

Senator JOHNSON. Those are the MACs, right?

Dr. BUDETTI. Those are the Medicare Administrative Contractors.

Senator JOHNSON. How quickly are they required to make payment when a claim is submitted?

Dr. BUDETTI. So, under the Medicare law, they are required to pay not sooner than 2 weeks and not more than 30 days. So there is a window after they get the bill. So it is a relatively quick payment requirement, but there is a window of a couple of weeks before the bill——

Senator JOHNSON. That is the MAC that does that?

Dr. BUDETTI. It is the Medicare Administrative Contractor that does that——

Senator JOHNSON. Is that 100 percent of CMS claims paid through the MAC?

Dr. BUDETTI. Of fee-for-service. On the Medicare fee-for-service program, the MACs do handle the claims, yes, sir.

Senator JOHNSON. OK. And then that would be different than for—Medicare Advantage is through private insurance.

Dr. BUDETTI. So Medicare Advantage is through private insurance, and other parts of Medicare are administered by the Medicare Administrative Contractors other than the DME for the——

Senator JOHNSON. Then who determines that, in 2011, for example, that 61 percent of the $9.7 billion that was paid by the MACs, who determines that 61 percent of that were improper payments?

Dr. BUDETTI. So, that is the CERT that you referred to, which is a completely different process that is not related directly to payment or directly to oversight, but to statistical measurement of what the improper payment error rate is, which we are required by law to measure and to report, and we do. And so that consists of a statistically valid national sample of claims so that we know how many of them are not being paid properly.

Now, improper payments span a very wide spectrum. At one end of the spectrum, of course, are fraudulent claims, and those are of great concern. But a lot of the improper payments are, I think as you referred to—I would not call them technicalities necessarily, but are for failure to follow the billing procedures, to document that the patient, for example, in a durable medical equipment situation actually had a physician contact and——

Senator JOHNSON. So why is that not caught in the original 17, or 14 to 30 days?

Dr. BUDETTI. So, just to be clear, Senator, the MAC—the initial payment screening does look at whether or not all the information that is required to be on the claim is there and whether it is appropriate, and then there are thousands and thousands of cross-checks on whether or not this is a medically unlikely claim, given the type of person and the type of claim, or whether it is within what is covered for a beneficiary. And many claims get screened out at that point.

But notwithstanding that, the claim may look good on its face, but behind the claim, there may not be the adequate documentation that——

Senator JOHNSON. OK. So what is the sample size on the CERT? In coming up with 61 percent, are we actually testing 100 percent and we are determining——

Dr. BUDETTI. No.

Senator JOHNSON [continuing]. Sixty-one percent, or are we——

Dr. BUDETTI. No. I think for all of——

Senator JOHNSON [continuing]. Testing 1 percent and——

Dr. BUDETTI. The last time I had the number in front of me, Senator, it was for all of the Medicare fee-for-service, and I believe it was on the order of 70,000 or 80,000 in the national sample. It——

Senator JOHNSON. Versus how many claims?

Dr. BUDETTI. Versus our billions of claims every year. But it is valid enough to project what the error rate is in fee-for-service claims across all of Medicare fee-for-service. And the specific question that you raised before about whether we are, in fact, going after that 66 percent improper payments—first of all, we certainly agree that any level of improper payment is not acceptable, and certainly a two-thirds rate of improper payments is not acceptable.

And so we use the information that we get when we find the improper payments. We use that in a wide variety of ways. We use it to work with the persons, the entities that submit the claims to make sure that they are, in fact, meeting the Medicare requirements in the first place. We——

Senator JOHNSON. OK. Well, again, I——

Dr. BUDETTI. OK.

Senator JOHNSON. I am already over, but let me——

Dr. BUDETTI. All right, but——

Senator JOHNSON [continuing]. Because I want to drill down on this——

Dr. BUDETTI. We would be happy to——

Senator JOHNSON. So then what percent of the improper payments are actually followed up on?

Dr. BUDETTI. So——

Senator JOHNSON. I mean, so that the auditing firms, what percentage of claims that are viewed as improper do we actually take a look at and try and do something about?

Dr. BUDETTI. So, in the national sample, all of the claims that are identified out of the 70,000 or 80,000 claims, all the ones that are identified as improper, which may be 7,000, 8,000, 10,000 claims that are identified as improper, all of those are followed up on. But that is a very small sample, because then from that sample, we extrapolate to the national total of improper payments.

Now, that is a very different issue, as I am sure you appreciate, that if you do a random national sample, you have identified what the number is, but you have not identified what the individuals are or entities are that you would need to go after——

Senator JOHNSON. Right. So I realize that directs your efforts——

Dr. BUDETTI. So, again——

Senator JOHNSON. Next question. What percent——

Dr. BUDETTI. So we have a separate set of contractors, yet another set of contractors called the recovery auditors, and one of the

things that drives where the recovery auditors look to recover overpayments is the findings from the analysis of where the improper payments are. So if there are improper payments that are being made in a certain type of service, then the recovery auditors can target that and go after it, and that is very in-depth.

Senator JOHNSON. OK. I think I understand that.

Dr. BUDETTI. OK.

Senator JOHNSON. Again, I am asking a question. What percent of the improper payments does Medicare do something with, I mean, to actually take a look at, audit, try and get recovery from? What percent is that?

Dr. BUDETTI. I——

Senator JOHNSON. Do you know or do not know?

Dr. BUDETTI. Well, we do something with all of the——

Senator JOHNSON. With 61 percent of all the claims that have been paid, you do something with it?

Dr. BUDETTI. We do something with it, but there is no way to seek to recover all of those because—first of all, if there is inadequate documentation or if there is a failure to submit the bills in a way that meets full Medicare requirements, that is something that the recovery auditors can target, but they cannot target every type of improper payment. They can only do whatever they can do.

But we use that information for restructuring our approach to dealing with the providers and suppliers, for dealing with beneficiaries, and, of course, we do look at the ones that look the most suspicious, and that is where we spend a lot of our time, looking at the ones that are suspicious for fraud or abuse.

Senator JOHNSON. OK. Thank you, Madam Chairman, for indulging me. I still do not understand. I mean, this is incredibly frustrating, preparing for this hearing, trying to understand the system——

Senator MCCASKILL. Welcome.

Senator JOHNSON [continuing]. And simply not—OK——

Senator MCCASKILL. We have a lot more to go.

Senator JOHNSON. Welcome to big government.

Senator MCCASKILL. We have a lot more to go. Senator Baldwin.

OPENING STATEMENT OF SENATOR BALDWIN

Senator BALDWIN. Thank you, Madam Chairman and Ranking Member Johnson, for holding this hearing. We do have a lot more work to do and I look forward to my service on this Subcommittee and the efforts we will take to protect taxpayer dollars by rooting out fraud, abuse in our government programs.

At a time when so many lawmakers are looking at cuts to Medicare benefits for seniors, I believe it is critically important that we do everything in our power to eliminate Medicare waste. According to the GAO, Medicare reported more than $44 billion in improper payments in 2012, and a recent RAND Corporation study found that fraud and abuse cost Medicare and Medicaid as much as $98 billion in 2011. Every Medicare dollar saved through fraud prevention and detection protects Medicare benefits for current and future generations, and we know that every dollar invested to fight Medicare fraud results in approximately $1.75 in savings, according to the Congressional Budget Office (CBO).

I really deeply appreciate the work that all of you do to maintain the integrity of the Medicare program, and I also appreciate the work of the Subcommittee to call attention to particular bad actors in the durable medical equipment industry. We must crack down on those companies whose business practices involve preying on our most vulnerable citizens and seniors.

You all have a really tough job to do and I want to look at this in a slightly different way, because we have to be careful about attributing the practices of certain bad actors within the durable medical equipment industry to the industry as a whole because there are certainly good actors out there. And in my home State, we have a number of excellent durable medical equipment suppliers, including a vibrant community of small businesses, mom-and-pop shops that have been serving Medicare patients and health systems for more than 40 years.

Along those lines, I want to perhaps ask you, Mr. Wilson, because you focus so much on the competitive bidding program as a tool for reducing Medicare spending, I support the overall goal of creating a fair marketplace for durable medical equipment suppliers and reducing costs, without question. However, I fear that the current competitive bidding program is designed in a way that will exclude many of Wisconsin's small businesses that have provided valuable medical products for many years.

So round two of the competitive bidding program has reached Wisconsin and the prices go into effect, as you referenced, in July. And I have heard from a number of respected companies—that are now completely shut out of providing services to Medicare beneficiaries for the next 3 years. It includes one company that has been serving Southeast Wisconsin for 39 years. Another, an independent business owner in Baraboo Wisconsin, serving principally a rural area who shares with me, she says, "I currently employ 13 full-time people and one part-time and I do not think our company is going to survive."

As the competitive bidding process expands over the coming months, I think we really have to monitor carefully the impact that this expansion has on small businesses in my State and throughout the country. And if the program hurts small business and patient access, particularly rural patient access, I think we have to continually evaluate and reevaluate. I also support consideration of other market-based bidding programs that will drive down Medicare spending without the adverse effects that I fear that the current program might have, or will have, on small businesses.

Before turning to you, Mr. Wilson, to talk about how you are monitoring the effects on small businesses, I also want to just note that we have to really be mindful about how our current audit practices impact patient access to needed medical products. One of our small prosthetic makers in the city of Madison, for example, who creates prosthetic legs, he reports that his Medicare claims have been all tied up in audits, and these claims have ultimately been approved, but in some instances, he has waited for over a year for payment. And as a result, many of his clients have had to wait significant times to receive their prostheses. For someone who crafts legs for some of our most vulnerable Americans, includ-

ing veterans, I think we have to make sure that our audit practices contemplate these challenges.

So, again, you have a really difficult task and I am very excited that we are focusing on ways to really get at the fraud. Chairman McCaskill, I have to say, when you were talking about the example of Med-Care, you may know that I was raised by my grandparents and I remember not so much in this area but in perhaps the charitable realm, that my grandmother would get solicitations—she was a very generous woman—would get all these solicitations for charities that sounded like legitimate charities, but they were really just a word different and that is very troubling to me. I am so glad for what you do, but I would like to hear what your safeguards are for making sure that the good actors still have a fair shake.

Mr. WILSON. Thank you, Senator Baldwin, for your comments and your questions. A few things I would say at the outset. I think that a lot of the problems related to fraud and abuse, related to audits, are symptomatic of a system where we pay too much and that generates sort of a dynamic of—and an incentive for—suppliers to bill for things that patients do not need. And I think, again, if we can bring the price down and deal with that underlying problem, I think that will go a long way toward some of these other things that we talked about.

With respect to small suppliers and competitive bidding, that is something that Congress in statute asked us to look at very closely and be mindful of in our programs, and we did some very specific policies to address small supplier issues, worked with the Small Business Administration (SBA) to establish a definition of a small supplier, built policies around that definition, such as a small supplier target where 30 percent of the contracts would go to small suppliers. In fact, in round two, it is 63 percent of the contract suppliers meet that CMS Small Business Administration standard. So we are very delighted to see that.

I think that it is true that the statute requires there be winners and losers under the competitive bidding program, so you do have other small suppliers that did not get a contract. One of the things that we are seeing now is many small suppliers working with contract suppliers as either a subcontractor or helping with distribution, patient set-up, patient education, so still being able to participate in the program and to earn a living.

Other small suppliers can continue to participate with Medicare by being a grandfathered supplier. They can continue to treat their existing patients for oxygen, other types of rental equipment. So, again, another opportunity to participate.

And they can also continue to provide other services that do not fall under competitive bidding. So there are opportunities to continue to operate and we hope that suppliers will take those. And, again, we are seeing it.

Rural suppliers—the program does not affect areas other than metropolitan areas and surrounding suburban areas at this point. So true rural areas are not affected by competitive bidding. Those suppliers can continue to operate. So I think that is a very important point to make.

And with respect to the supplier that is having difficulty with an audit for the prosthetics that they provide, if your office would like

to provide us with information, that is something we would be happy to look into. I could not say what the particular issue is, and I may be speaking for Dr. Budetti, but I am happy to look into that.

Senator BALDWIN. We will take you up on that. Thanks.

Senator MCCASKILL. So let me see if I can correctly state this. Although I have different numbers about what the total is that you spend on medical equipment, I think it is fair, if everyone would agree, that we can use a ballpark figure of $10 billion. Any problem with that from any of the witnesses? OK. Is that fair, ballpark, $9, $10 billion?

Mr. WILSON. Ballpark.

Senator MCCASKILL. OK. $9, $10 billion. OK. So your statistically valid sample says your improper payments in that universe is 66 percent in 2011, correct?

Dr. BUDETTI. Yes.

Senator MCCASKILL. OK.

Dr. BUDETTI. It is around 66——

Senator MCCASKILL. So, now, for fee-for-service, the same statistically valid sample showed improper payments of 8.5 percent, correct?

Dr. BUDETTI. For things other than DME, yes.

Senator MCCASKILL. OK. So DME is 66 percent and the rest of it is 8.5 percent.

Dr. BUDETTI. Right.

Senator MCCASKILL. OK. You are in trouble.

Dr. BUDETTI. We are.

Senator MCCASKILL. This is a big problem.

Dr. BUDETTI. We acknowledge that——

Senator MCCASKILL. OK.

Dr. BUDETTI [continuing]. And that is why we have——

Senator MCCASKILL. Now, let us take it one step further.

Dr. BUDETTI [continuing]. Seriously.

Senator MCCASKILL. In 2011, our investigation shows, based on facts and figures you gave us, that you recovered $34 million in improper payments on DME in 2011.

Dr. BUDETTI. I believe that is the right number, yes.

Senator MCCASKILL. OK. So we have a ballpark $10 billion. Let us say $9 billion to be fair. We know 66 percent of it is improper in some regard. It may be technical. It may be fraud. It may be all kinds of problems there. And we are getting $34 million back.

Now, these auditors, these recovery auditors, that is terrible. So I have to assume they are not working on a contingency.

Dr. BUDETTI. The recovery auditors do work on a contingency——

Senator MCCASKILL. OK. Well, I cannot imagine how bad they must be.

Dr. BUDETTI. Well, I think it has to do with which areas they are, in fact, looking at——

Senator MCCASKILL. Doctor we have 66 percent improper payments on $10 billion and they find $34 million? That is like——

Dr. BUDETTI. Senator, let me——

Senator MCCASKILL. That is like me seeing a penny over there and saying, boy, I picked it up. Pay me for it. How much of their

contract is based on how well they do and how much of it do they get regardless of whether or not they are complete failures at it?

Dr. BUDETTI. So the recovery auditors look at all the possible sources of overpayment recoveries as well as, of course, making up for underpayments where we underpaid somebody across the Medicare fee-for-service program. So DME at $10 billion does have a very high overpayment rate, improper payment rate. There is no doubt about that.

But when I said, Senator, to Senator Johnson earlier that we were looking at three areas within DME that account for about half of that improper payment rate and that is oxygen supplies, glucose monitoring supplies, and nebulizers with related drugs. So these are generally legitimate services that went to legitimate beneficiaries, to a large part, and what we need to do is make sure that the documentation and the billing practices and all of the other approaches are correct. And then we have individual targets. We have individual initiatives to deal with each one of those. You pointed out——

Senator MCCASKILL. OK, then let us break this down this way.

Dr. BUDETTI. OK.

Senator MCCASKILL. I get the point you are making. You are saying some of this is technical and it is not really somebody ripping off the system. It might be technical violations——

Dr. BUDETTI. Right.

Senator MCCASKILL [continuing]. Because of the areas where so many of them are. Let us do it this way. When you did the national sample and statistically valid, did you ask them to break out a statistically valid sample of how much of that was, in fact, fraud and waste?

Dr. BUDETTI. So, that has been one of the areas that we have been working on, because the way that the statistical sample is structured and the way that it measures improper payments is not a very sensitive tool in terms of actually looking at fraud.

Senator MCCASKILL. Well, then why do we have it? What is the point if we are not going to get the money back? Why are we auditing anything if we are not trying to get the money back? This is like a bureaucratic dance if it does not mean anything. This is a giant waste of money, that we are doing a statistically valid sample, we are figuring out a 66 percent figure, but we are collecting $34 million. Either you are sampling wrong—and I am a former auditor—either you are sampling wrong and you are not focusing your statistic sample on trying to find the fraud and waste, or your auditors are complete failures in going after the money.

Now, the next question is for you, Ms. Stanley. We now know that we have 66 percent that is wrong some way. Now, you are supposed to be figuring this out. Why, when you know that somebody has more than 50 percent of the documentation they have sent in is wrong, why do you not quit paying them until you figure it out?

Ms. STANLEY. And that is really, what we do in——

Senator MCCASKILL. No——

Ms. STANLEY [continuing]. From the ZPIC perspective. Well, I am just talking about from the ZPIC——

Senator MCCASKILL. OK. When can you quit paying them?

Ms. STANLEY. Once we have a credible allegation of fraud, we can—or we have an overpayment that we know exists. We may not know exactly——

Senator MCCASKILL. OK. Let me ask you this. Let me give you a hypothetical.

Ms. STANLEY. OK.

Senator MCCASKILL. It comes to your attention that someone has billed Medicare for a sleep apnea machine for someone who is dead. Does everything stop in terms of paying that provider at that moment?

Ms. STANLEY. We would, of course, verify, in light of Senator Baldwin's comment about that whole balancing act of making sure that this is, as you say, a bad actor——

Senator MCCASKILL. Really dead?

Ms. STANLEY. Well, we would want to verify that this is not just an error on their part. What normally we would see is—you are going to see that happen more than once. You are not going to just see that on one claim. You are going to know that this is a repeated thing——

Senator MCCASKILL. When do you pull the plug?

Ms. STANLEY. As soon as we have a credible allegation——

Senator MCCASKILL. So, what percentage of the cases that your Zone has worked, what percentage do you pull the plug on?

Ms. STANLEY. I do not know if I can give you a credible number of that——

Senator MCCASKILL. Dr. Budetti, when are they allowed to pull the plug? When can they say, we are not paying you any more. There are too many problems—and especially with this analytics you are going to get. Do you all have the procedures in place? You say you are going to have advance analytics.

Dr. BUDETTI. Yes——

Senator MCCASKILL. At what point in time do you have the authority, and do we need to give you more authority to say, you are done. We are not paying you until we figure this out.

Dr. BUDETTI. So, we do have very strong authority that was under the Affordable Care Act, which Ms. Stanley referred to, which is to suspend payments, ending the investigation of a credible allegation of fraud. And when we have a credible allegation of fraud, then we consult with the Office of Inspector General and if there is, after that consultation, we are in a position then to suspend payments. Suspending payments is an intermediate measure. It stops the payments at that point in time, but we still have to do all of our additional work to see whether or not that particular supplier or provider should be kicked out of the program, whether their billing privileges should be revoked——

Senator MCCASKILL. Right.

Dr. BUDETTI [continuing]. Whether we should refer them to law enforcement——

Senator MCCASKILL. And maybe——

Dr. BUDETTI [continuing]. For additional investigation——

Senator MCCASKILL. Right, or maybe we go back and try to get some of the money.

Dr. BUDETTI. And, in fact—well, when we suspend payments, then, depending upon the kind of claim that is coming in and

whether it would otherwise have been approved for payment, that money can go into an escrow account that we then have if later on we can declare an overpayment exists and we can collect that overpayment. So that is a very useful tool. It is one of the tools that we use.

Another way of stopping payments involves looking at the claims and not paying them until they have been reviewed, so pre-pay review also can stop the payments until the claim is being reviewed.

And then, of course, there is also, as I mentioned before with the payment contractors, the MACs, there are many ways that we can introduce ways to block payment based upon the experience that——

Senator MCCASKILL. Well, that all sounds good in theory, except we are going to followup on this subject over the next 2 years. It does not do any good for us to have all this in place if you have these kind of numbers in terms of money going out the door.

And I need to finally ask this question and then I will turn it over to Senator Johnson, and I will probably have some more after he finishes, but how are the auditors paid? Can you legally put out a proposal that you will hire people to go after improper payments in the durable medical equipment area and you will not pay them anything, except they get 10 percent of everything that they recover?

Dr. BUDETTI. So that is the Recovery Auditor Program that is in statute, and that is how the recovery auditor contractors, what are called the RACs——

Senator MCCASKILL. So they get nothing if they do not recover anything.

Dr. BUDETTI. That is correct. Their payments are based upon their recoveries, and they work with the Centers for Medicare and Medicaid Services in terms of their priorities——

Senator MCCASKILL. Well, how many contractors do you have, if you are only getting $34 million?

Dr. BUDETTI. So, Senator, one of the aspects of this that maybe I have not communicated adequately is that improper payments are payments that were improper when they were made, but many of those improper payments could be proper payments if the billing was correct or if the documentation was correct——

Senator MCCASKILL. But you do not know what percentage?

Dr. BUDETTI. Well, actually, we do——

Senator MCCASKILL. What is it?

Dr. BUDETTI [continuing]. A very high percentage of them—and that is why, when we review them, we learn from the experience——

Senator MCCASKILL. OK. What percentage of the payments you are making should not have been made, based on a fraud, waste, or abuse? What percentage of the 66 percent? Half? A third? Twenty percent? Do you have any idea?

Dr. BUDETTI. I can tell you that the two numbers are very different. We believe there is waste and fraud——

Senator MCCASKILL. You do not know the number, Dr. Budetti, do you?

Dr. BUDETTI. Senator, fraudsters are very good at making their claims look real——

Senator MCCASKILL. I agree.

Dr. BUDETTI [continuing]. So our system for measuring improper payments is not designed to—and is not really appropriate for measuring fraud. We are separately designing an approach to measure——

Senator MCCASKILL. Where is the system that measures the fraud, then? That is what I am interested in.

Dr. BUDETTI. So——

Senator MCCASKILL. I want to get the money back.

Dr. BUDETTI. I totally agree with you, Senator. Actually——

Senator MCCASKILL. It does not appear that you are that focused on that, because it looks like you have this bureaucratic system where you are figuring out improper payments, and now you are trying to tell me, well, never mind that big number. It does not really matter because, really, that is just paperwork and it is not really fraud.

That is what we are here about today. We are here to figure out how to get the money back from people who have ripped people off and how we keep our money being spent on that in the future. And if your systems now cannot tell you those numbers, if you cannot sit there as the Head of Integrity for CMS and tell me, we think about 20 percent of the money going out the door every year should not be going out the door, if you have no idea what that number is, then there is no integrity in your program. You are in charge of knowing whether there is integrity and you are telling me you do not know what percentage of the 66 percent is even money that should not have been paid.

Dr. BUDETTI. Senator, I could not agree more with the direction you are going in terms of our job is to protect the Trust Funds and protect the taxpayers and to make sure that money is not paid improperly, and certainly to go after the people who are, in fact, stealing from the programs.

We have been, and we are working on a separate approach that is designed to measure probable fraud. We cannot just go out and ask people, did you commit fraud? We cannot do an estimate that works that way——

Senator MCCASKILL. I can show you how to do this. Prosecutors can.

Dr. BUDETTI. Prosecutors could, yes.

Senator MCCASKILL. We catch fraudsters all the time. And, by the way, you have——

Dr. BUDETTI. Absolutely right.

Senator MCCASKILL [continuing]. So much documentation here. I look at some of these letters that just were sent in to us, frankly, some of this is like taking candy from a baby. And if the Federal system is not interested in doing this, you have State and local prosecutors I think you could get interested.

I will turn it over to Senator Johnson.

Senator JOHNSON. Thank you, Madam Chairman. By the way, good questions. I have the exact same questions.

I think what we really need to do is work together and work with CMS to get the answer to your question in terms of what percentage really is fraud related? How much of the improper payments really are paperwork violations, technicalities that are actually ad-

dressed by the suppliers and then get paid? I mean, we are missing some basic information. Again, welcome to big government.

Also, I appreciate Senator Baldwin's comments about not painting with a broad brush in terms of the bad actors. We want to definitely discipline and go after bad actors versus the quality suppliers throughout the industry.

In that vein, we were working with the American Association for Home Care to try and get answers to some of these questions, get their perspective, and they sent me a letter[1] I would like to enter into the record, with unanimous consent.

Senator MCCASKILL. Absolutely.

Senator JOHNSON. Thank you. An interesting statistic that I came up with, also, that we found out, is that when the payments are being adjudicated, 53 percent that were termed "improper" or where there was—I am not exactly sure what this represents, but 53 percent by Administrative Law Judge (ALJ) are actually overturned. So, in other words, if they were basically judged by CMS to be improper, now 53 percent when adjudicated are actually proper. So I am not quite sure what that tells us, but we have a problem here.

What I would like to do is—again, this is welcome to big government—so, Ms. Stanley, you have some private sector experience, so I would like to talk a little bit about the difference between the problems we are seeing here in terms of how do we get our arms around, how do we control waste, fraud, and abuse in a public payment system, a big government system, versus how does the private sector do it, because we are talking about Medicare fee schedules paying three to four times the rate, I guess, of private insurers. And I know a lot of people like beating up on private insurers, but they do something to control that.

Can you just speak, in general, to the difference in the type of fraud that private insurers are dealing with versus the Medicare system?

Ms. STANLEY. I will try. I think that a lot of the issues are similar that you see on both sides. One of the big differences that I noted when I came to Medicare was that, we had so much control, I guess, for lack of a better word, over our panel of physicians on the private side. If you are an Health Maintenance Organization (HMO), you are controlling kind of that market and who you are letting into that program.

I think that CMS has made extreme progress in heading in that direction with more control over provider enrollment, especially around DME. The National Supplier Clearinghouse that Dr. Budetti mentioned really has taken, I think, just leaps and bounds of better controls around how they are looking at providers and treating it much more like the private side.

Senator JOHNSON. OK, but in the private sector, a private insurance company does not make payments on claims and then auditors come in there and say, well, boy, 66 percent of those were improper——

Ms. STANLEY. Well, you are right.

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[1] Letter submitted by American Association for Home Care appears in the Appendix on page 90.

Senator JOHNSON. I mean, what percentage would it be?

Ms. STANLEY. One of the advantages—I would not want to answer that, but one of the—because I have been out of it for some time——

Senator JOHNSON. OK.

Ms. STANLEY [continuing]. But one of the big differences, I think, as well, is things like precertification. Private insurers will set up and they will say, look, in order to get this supply or this surgery, we are going to have you precertify. Medicare is a fee-for-service program and so we have not went in that direction. Of course, on the managed care side, you have HMOs manage care for Medicare, but under the fee-for-service side——

Senator JOHNSON. But, also, you just have private insurance. Again, I know that some people just really hate the thought of profit, but it is a pretty strong discipline in terms of controlling costs, is it not?

Ms. STANLEY. Well, absolutely——

Senator JOHNSON. And the private sector——

Ms. STANLEY [continuing]. Is looking at——

Senator JOHNSON [continuing]. Does just a far better job controlling costs, preventing fraud within the private reimbursement system. Again, if you want to really know the root cause of the problem with the out-of-control health care spending in general, it is because we have separated the consumer of the product from the payment of the product. We did that back in the 1940s and we started the third-party payer system. Whether it is government paying for it or insurance companies paying for it, the consumer of the product, by and large, does not care what something costs because they really do not have that much skin in the game. Yes, there are deductibles. There is co-insurance. But, in general, just give me the best and we end up with that basic result.

In terms of how the private sector operates, in terms of how they control those costs, talk about their auditing system versus what you are doing.

Ms. STANLEY. Wow. I do not know that it is that different. I mean, many times, they are responding to complaints. They are doing some data analysis. In some cases, to be honest, it is at least, and again, I have not been on that side of the house——

Senator JOHNSON. OK. So let me change gears, then.

Ms. STANLEY [continuing]. For 13 years.

Senator JOHNSON. Let us talk about——

Senator MCCASKILL. She was about to say something nice about——

Senator JOHNSON. Oh, I am sorry. It is——

Senator MCCASKILL. Let her say something——

Senator JOHNSON. Oh, OK. Sure. Well, I am running out of time.

Senator MCCASKILL. You can take more time——

Senator JOHNSON. No, go ahead.

Ms. STANLEY. Go ahead. That is fine.

Senator JOHNSON. No, go ahead if you were going to say something really nice.

Ms. STANLEY. I was going to say that I think that, in some ways, Medicare is so much more sophisticated. I mean, when I came from the private side, we based everything on how Medicare designed

their payment structures, and that is really what we based a lot of our policy and procedure on because Medicare was really so sophisticated in terms of the specific policies and in looking at medical necessity and those kinds of things, not necessarily talking about the payment specifically, but just the way that you are administering that.

And I think that looking at the data analytics side, the fact that we are trying to go, CMS is looking more at risk-based, which sort of gets to your point, of trying to look at where is the highest risk to this program? Where are we going to get the biggest bang for our buck, and let us focus those resources on those areas. That also keeps us from sort of hounding those physicians or suppliers that are trying to do the right things.

Senator JOHNSON. Let me just move into the private sector side of the public system here and Medicare Advantage. Talk about the fraud that we are seeing in Medicare Advantage in terms of reimbursements there versus what we see in Medicare and Medicaid, because, I mean, my understanding of that is that is a, I guess, a voucher program, something like that, where seniors are actually buying private health care plans and they have a little more skin in the game that way. Do we see the same problem in that, which is about a $232 billion a year program, is that about accurate, with Medicare Advantage? Dr. Budetti.

Dr. BUDETTI. So, the improper payment error rate, which is what we do measure across Medicare, is—I am trying to come up with the number—I think it was on the order of 11 percent this year. But, again, that is not a measure of fraud.

Senator, because you are so interested in the private sector, and I would be delighted to provide you with more information on this, we have launched over the past year and recently really moved into an advanced phase of an active ongoing partnership with the private sector, with health plans, with the Health Care Anti-Fraud Association, with the States. We are all now working together under a Health Care Fraud Prevention Partnership, and this will involve everybody sharing information on who is perpetrating exactly which kind of scams. We are very encouraged. The private sector plans and associations that are working with us are extremely enthusiastic about this.

We are building this as a long-term interaction that will mean that fraudsters will not be able to, for example, bill one health plan for 8 hours a day, bill another health plan for 8 hours a day, bill Medicare for 8 hours a day, and bill Medicaid for 8 hours a day and get away with it because nobody is seeing 32 hours of billing because we will be sharing the information among all of the payers and building the sophisticated analytics around the shared information.

And so this is a very important step forward, that if you would be interested, we would be delighted to provide you with more information on.

Senator JOHNSON. OK. Again, that sounds like a positive cooperation and coordination. But, again, it is not speaking to the benefit of utilizing more of a private sector model, where individuals have more skin in the game or more control over what they are spending, making wise consumer choices, versus the govern-

ment just coming up with a fee schedule that is paying three or four times the cost of different types of products.

My concern is you will never made that system work, and I think that is really what we are seeing here in this hearing. Medicare is how many years old, and it is just coming to grips with some of these, really, overpayment issues.

But, anyway, that is enough for my time right now. Thank you.

Senator MCCASKILL. Let me talk about the specifics of some of the complaints that I got from constituents. It is my understanding that the rule does not allow telephone solicitation, correct, without some kind of previous permission from the Medicare member that is being solicited?

Dr. BUDETTI. That is correct.

Senator MCCASKILL. OK.

Dr. BUDETTI. Cold calls are not allowed.

Senator MCCASKILL. Cold calls are not allowed. Clearly, we have received a lot of complaints about cold calls. I think we got almost as many as you did, according to your information you gave us. You all briefed us that you had 70 complaints that were investigated last year. We got more than that—I am sure you got many that were not investigated, but you had 70 that were investigated.

Has a DME supplier ever been excluded from the program based on being caught doing this?

Dr. BUDETTI. I believe you are aware from the information we provided, Senator, that growing out of the 75, I believe it was, that were investigated, most of those led to various kinds of corrective actions. There were problems, but most of them led to various kinds of corrective actions. One of the suppliers did, in fact, have their billing privileges revoked, but then was able to demonstrate that they were stopping and that they were engaging in proper conduct and so they were readmitted into the program.

But I point out that there are lots of other consequences or people who are engaging in unlawful telemarketing to Medicare beneficiaries. In particular, any claims that they subsequently submit that were generated by that unlawful telemarketing are false claims against the government, and both the telemarketers and the suppliers can be liable criminally, civilly, for submitting false claims. And recently, there was a case that was reported where, I believe it was close to $18 million was paid in precisely that circumstance.

So in addition to the work that we do to impose administrative controls and corrective actions, there are lots of other consequences for telemarketers if that leads to false claims against the government.

Senator MCCASKILL. I would really like a breakdown of how many immediate consequences resulted from a violation of the telemarketing laws, because this is one of these areas where I really believe a zero tolerance would have a wonderful deterrent effect. You all have an awful lot on your plate.

And I do want to compliment you. I know I am tough on you, Dr. Budetti, but I do want to compliment you in that, overall, the administrative costs of Medicare are very reasonable. In fact, I believe—and this is where my friend and I, we agree on going after fraud and waste, we probably have some other differences of opin-

ion—I am aware that the administrative costs for Medicare Advantage are higher than Medicare, that, in fact, we spend more on overhead on Medicare Advantage than we do on the basic Medicare program, and that was—Medicare Advantage came about because the private sector came and said, give us Medicare. We can do it cheaper.

Well, as it turned out—in fact, the $500 billion that is thrown around in political campaigns is all about pulling back some of that money that has enhanced the bottom line of those private Medicare Advantage companies that said they could do it cheaper, and it turned out they could not. They did not do it cheaper. It was more expensive, not less expensive. And that is the $500 billion that I think the Republicans and Democrats agree on, because it is in everybody's budget. It just becomes the whipping post at election time.

I really am worried about whether or not we are sending the right signal about the tolerance of this and whether or not cases are being criminally prosecuted. Do you know, Dr. Budetti, what percentage of the cases that are referred to law enforcement end up in a civil settlement versus a criminal conviction versus time behind bars?

Dr. BUDETTI. With respect to telemarketing per se or with respect to wider——

Senator MCCASKILL. The whole caboodle, fraud and DME.

Dr. BUDETTI. I do not have that breakout, Senator, but I would be delighted to work with our law enforcement colleagues and get you a response.

Senator MCCASKILL. I found out the hard way in this Committee that when I first talked to the U.S. Immigration and Customs Enforcement (ICE) about how many employers had gone to jail for knowingly hiring undocumented immigrants, they had no idea. And the reason they had no idea is because, frankly, they were not doing it. They did not want to keep track of it because it was not very good.

So I know if you keep track of it, we can hold you accountable. And I would certainly urge you to get that information to us and then have it in a way, just like you tracked how many overall suppliers you have, track how successful you are at putting people in prison that do this, not saying, we are going to slap you on the hand and we paid you $140 million and you gave us five, so we are going to call it a day. You have probably got money stashed no telling where, and we are going to take $5 million from you and you are going to walk away, and before you know it, you will be in a fancy place somewhere else with all the money you have made off this program and you are never going to spend a day behind bars.

Dr. BUDETTI. Senator, I can tell you that the Health Care Fraud Prevention Enforcement Action Team and the associated strike forces have been extremely successful in both increasing the likelihood of convictions and also the speed with which convictions are occurring——

Senator MCCASKILL. That is terrific.

Dr. BUDETTI [continuing]. And I will be delighted to get you the detailed data on that. But I must say, I think that what you just

expressed, I can identify with many of the comments you just made, Senator.

Senator MCCASKILL. Thank you. And why was the rule scaled back just to include phone calls? Why can we not include e-mails and text messages and all of those? Is this over-hyper legal counsel? Is that what this is?

Dr. BUDETTI. It is—I would never use that phrase, Senator.

Senator MCCASKILL. I can. I am a lawyer. [Laughter.]

Dr. BUDETTI. We do not have the statutory authority to regulate beyond telephone marketing, and we would be delighted to discuss that with you further if you would like to.

Senator MCCASKILL. And I should know—and I will check—the lawyer said the underlying statute specifically says telephone only?

Dr. BUDETTI. Yes. We are limited to telephone only. That is the way——

Senator MCCASKILL. And when was this all written?

Dr. BUDETTI. I do not know the date of that, but I will be happy to get you all the details.

Senator MCCASKILL. Shame on you.

Dr. BUDETTI. We would be delighted to discuss this with you in more detail, Senator——

Senator MCCASKILL. Yes, because as you know, our challenge on Medicare is the demographics, and I can assure everyone that in the not-too-distant future, you are going to have a whole lot of Medicare participants that are relying more on e-mail and text message than they are phone calls, if my life is any example. I am not there yet. I do not even want to say how close I am because it is, frankly, frightening to me that I am going to be there before too long. I really think we have to do whatever is necessary.

So I would look for some guidance from you on specific statutory language you need to prohibit this cold calling in any form.

Dr. BUDETTI. So, we would be delighted to work with you and your staff and the Subcommittee and any interested members, Senator.

Senator MCCASKILL. How about the bonding? I know we have bonding now. How successful have we been at going after these bonds?

Dr. BUDETTI. The durable medical equipment suppliers are required, as part of their enrollment process—and we have verified that this is the case—to have security bonds in place. The security bonds have been in place, I believe it is now since 2009, and when we get to the point where there is a debt that has not been collected, then we are able to move against the security bonds.

We have, in the past a little over a year been implementing the collection procedures against the surety bonds. We have our work cut out for us to improve that process and to make sure that we are going against it. Fortunately, although the bond may have been held by somebody who has disappeared and who has no assets, the security—the surety is still there that holds the surety bond, and so we can go after the surety bonds. And so this is an area that is very active in terms of improving our process and improving our collections against the surety bonds and we are pursuing this with a great deal of energy.

Senator MCCASKILL. I would like the accountability metrics on that, too. I would like to know how many bonds we have gone after, what percentage of the bonds have been recovered, because I want to make sure that we are building the data, because I believe that the Secretary has the authority to increase the size of those bonds——

Dr. BUDETTI. That is correct.

Senator MCCASKILL [continuing]. And if we do not have that data at the tips of our fingertips, then there is really never going to be a time she is going to increase those bonds because she is not going to have the data to support the decision.

Dr. BUDETTI. Senator, I share that entirely, and we are in the process now of building the reporting and data systems so that we can do exactly what you just said.

Senator MCCASKILL. OK. That is great. I believe you covered the competition very well, and I know we are going to take a lot of the excess out with that.

I am happy now to turn it over to Senator Johnson, if you have any other final questions.

Senator JOHNSON. Yes. Thank you, Madam Chairman.

As long as we are talking about different types of certification, do you have the statistics on how many suppliers there are? I have seen 100,000. I have seen 15,000. How many suppliers are there——

Dr. BUDETTI. We are down to about 96,000 now, Senator.

Senator JOHNSON. Ninety-six thousand. How many of those—do you have the statistics on terms of how many are certified, how many have been certified with a site visit?

Dr. BUDETTI. So, all of those suppliers went through the initial enrollment process and screening, and then when they were subject to surety bonds a few years ago and now are subject to advanced scrutiny, enhanced scrutiny under the Affordable Care Act and revalidation. We are in the process of revalidating all 1.5 million——

Senator JOHNSON. Is that like a desk revalidation, though, or is it site visits or——

Dr. BUDETTI. No, Senator. They are all subject to unannounced site visits, and when the National Supplier Clearinghouse notices any kind of elevated fraud risk for a given supplier, they raise the likelihood of scrutiny of going back and doing——

Senator JOHNSON. OK. Again——

Dr. BUDETTI [continuing]. Subsequent site visits and so forth.

Senator JOHNSON. Subject to is different from actual site visits. So I——

Dr. BUDETTI. No——

Senator JOHNSON. Let me just ask——

Dr. BUDETTI. That is the 86,000 site visits that I referred to, Senator, so far.

Senator JOHNSON. Eighty-six thousand site visits. OK. Good. So we may just ask for more detail on that a little later on.

Dr. BUDETTI. Sure.

Senator JOHNSON. We talked about some of these telemarketing scams and the requirements that you have to have been a customer. I know one of the companies we invited has been in the acquisition mode. What is the law? What are the rules governing a

business that acquires a bunch of other businesses that have a bunch of customers? Does that become part of their customer base so that they can take those Medicare numbers and apply them to their entire product line against all their companies?

Senator MCCASKILL. That is a good question.

Senator JOHNSON. Do you know if that is?

Dr. BUDETTI. So, I think it would depend on whether they are going to be essentially a new supplier or because they are all subject to the enrollment and oversight responsibilities. I think that our ability to track that will be greatly enhanced with some enhanced proposed rules that actually we are announcing today, Senator. And so—but the companies—it is a marketplace. The companies can engage in the transactions that you mention. But then they are going to be subject to the exact same kind of scrutiny. They cannot just simply——

Senator JOHNSON. I understand, but that is a way to dramatically increase your reach in terms of being able to telemarket to customers, because now you can legally do it because you bought a company who has a lot of customers and now you can spread that over your entire product line, correct? OK.

Ms. Stanley, let us talk a little bit about the private sector. You had mentioned those six frauds. Do those same six types of frauds—are those commonplace in private sector insurance companies, I mean, doing the exact same thing, and how prevalent?

Ms. STANLEY. Well, it kind of depends on the individual insurance plan. If you are talking about an HMO, where they are doing precertification, you are not going to see things like services not medically necessary because you have already screened that up front. But most of the same thing with, say, the example that I gave of hospice——

Senator JOHNSON. I mean, telemarketing fraud? Is that common in private insurance?

Ms. STANLEY. Again, I have not done that——

Senator JOHNSON. Probably not. What about services not provided? I mean, generally, are not private sector—again, I bought health care. We were paying these claims. I——

Ms. STANLEY. I know that we would have—again, this has been 13, 14 years ago—we would certainly have instances of services not provided, but I think moreover it was more focused on either the coordination of benefits issues around who was supposed to be paying and also—some of these things, however, are definitely——

Senator JOHNSON. But it is——

Ms. STANLEY. You see them on both sides.

Senator JOHNSON. It is safe to say, though, that the instance of fraud is far less in the private insurance market, correct?

Ms. STANLEY. I do not know the answer to that.

Senator JOHNSON. OK. Let me just conclude with just a couple more facts. You raised the $500 billion figure, so let me talk a little bit more about that, because that was an old figure. What we are looking at right now in terms of the health care law is when it was originally passed, it was going to cost a trillion dollars over 10 years. The current budget window is about $1.7 trillion. And when it really kicks in 2016, it will cost about $2.4 trillion over 10 years. Again, that is going to be, I am afraid, another government pro-

gram that may not be particularly efficient in terms of how the money is spent.

It was going to be financed by about a half-a-billion dollars' worth of taxes, fees, and penalties, which gives you in the first 10 years about a half-a-trillion dollars' reductions in payments from Medicare in some way, shape, or form, Medicare Advantage. In the second 10 years, I believe it was going to be about a trillion dollars in taxes, which means—that is the $716 billion of reduction from Medicare, Medicare Advantage, in some way, shape, or form. In the full implementation, 2016 through 2025, now you are talking about $1.5 trillion of taxes, and that is leaving about a trillion dollars coming from somewhere, I guess, Medicare, Medicare Advantage. That concerns me.

When I was at dinner with President Obama—listen, I appreciate the fact that he reached out and we start that process of building relationships and start solving these problems—it was interesting during that dinner when he laid out the extent of the problem. Pretty accurate, I thought. In terms of the budget, he said it is health care spending, which it is. And in particular, he said, the problem we have reforming Medicare is that for every dollar that Americans pay into the system, they are going to be getting about three dollars out in benefits. He also went on to say that most Americans do not understand that, which I agree. I do town halls all the time. People do not understand the extent of the problem.

Now, the only way you are going to fix a problem is you have to first admit you have one and you have to properly define it, and that is what we are trying to do here today, just on the fraud. We are trying to get to the definition of the problem. But if you go back on a macro basis and you look at the enormous problem, the enormous challenge facing Medicare, I am highly concerned.

Madam Chairman, again, I appreciate the bipartisan effort here. I think as the first act of bipartisanship, we need to come together, figure out what we agree on, agree on the facts and figures, whether it is in this micro problem in terms of—overall, it is a big problem, but it is small compared to what we are talking about here, a dollar going in and three dollars going out. Now, I really wish the President would publicly tell the American public what he told us in private, because all I have heard him say publicly is that we just need modest reforms to Medicare. I think the result of this hearing is that we need far more than modest reforms to Medicare.

So with that, again, Madam Chairman, I really appreciate this hearing. I want to keep working with you on this. I want to get to the bottom of what is happening with waste, fraud, and abuse in the Medicare system. Thank you.

Senator MCCASKILL. Well, I think we can, and I think we can agree for a lot of reasons—I have heard the President say that publicly. I have heard him say that we have the average recipient of Medicare services is getting three times as much in benefits as they have paid into the system. I think he said it a number of times in public.

Senator JOHNSON. OK. I stand corrected.

Senator MCCASKILL. Yes. And I think we all know that is the problem, and part of that is, in fact, incentivizing the system ap-

propriately, and I agree with you about making sure that we have skin in the game, making sure that we have means testing, making sure that we have a system that does not allow bad actors to take advantage of the fee-for-service scenario. And some of it is just the business models that we have allowed to buildup around Medicare, where the more you do, the more you make—not how healthy you are, but the more you do.

I have told this story before, and I will close the hearing with this. You would not believe how hard it was for me to get my mother to say to her doctor, "I had blood work 3 days ago at another doctor. I am not going to do it again." She said, "Well, I cannot say that to the doctor." I said, "Yes, you can. You have had enough blood work for this 10-day period. You do not need five sets of blood work in a month. We are paying for that. You do not need it."

But the doctors know that every time they do that, that is something Medicare is going to pay for. And until we get this primary care system where we have a lot more oversight from beginning to end and more of a continuum of care with the emphasis on healthy, the emphasis on skin in the game, I think we are going to continue to struggle in trying to bring these health costs under control.

But this is a big deal, because not only does it cost us a lot of money, it is rewarding exactly the kind of behavior that we need to be putting in prison in terms of this fraud, and particularly the fraud.

So I look forward to working with you, Dr. Budetti and Mr. Wilson and all of the—I will use the acronym now—ZPICs—and the MACs. I would love to meet the MACs. I want to know if they are getting only paid for what they recover. They need to hire—there are some really good auditors out there that could make a lot more money if they went to work for them, because I guarantee you, there is a lot of money to be made on going after this money. Maybe they do not have the tools. Maybe I need to learn what tools they need they do not have in terms of getting after these improper payments that are recoverable, because you are doing a miserable job at getting the money back in the door.

So I will look forward to working with you and I will look forward to you having clear and crisp answers to what is the extent of money that is being paid that should not be paid in DME, in medical equipment. How much is going out the door that should not be going out the door? I would love that number. Surely we can come up with a number that you are comfortable with, and then we can start measuring it and see if we cannot bring it down. I would love to see us save a billion dollars in the next 2 years. That is a goal that I would like us to set and I think it is achievable if we all work together on this, and I look forward to working with Senator Johnson.

We will consider compelling the witnesses' appearance that did not appear today. I think that we want to be very careful about this because we do not want to have government being onerous or overreaching when it comes to asking people to appear in front of the Senate for Committee and oversight work. I will look forward to visiting and getting the counsel and advice of the Ranking Member on that, as to how we proceed. I do know that there is a lot of private sector that is making a lot of money off the government,

and part of our job in terms of accountability is making sure that we are getting the answers from those companies.

I have found in the contracting world that when I did listen to the companies, not only did I figure out how we could save money, I figured out how to make it easier for the majority of the contractors that do business with the government that are doing the right things for good value and are saving us money. The privatization in many instances does save us money and I want to make sure that I always mention that. But getting insight from the private sector is very important to this oversight work when those companies do depend on the government for their cash-flow and for their profit and loss (P&L).

So I will look forward to working with you all. I want to thank the staff for their hard work on this. I certainly want to thank Senator Johnson, and this hearing is adjourned.

[Whereupon, at 11:59 a.m., the Subcommittee was adjourned.]

OVERSIGHT AND BUSINESS PRACTICES OF DURABLE MEDICAL EQUIPMENT COMPANIES, PART 2

WEDNESDAY, MAY 22, 2013

U.S. SENATE,
SUBCOMMITTEE ON FINANCIAL AND CONTRACTING OVERSIGHT,
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:02 p.m., in room SD–342, Dirksen Senate Office Building, Hon. Claire McCaskill, Chairman of the Subcommittee, presiding.

Present: Senator McCaskill.

OPENING STATEMENT OF SENATOR MCCASKILL

Senator MCCASKILL. Welcome. This hearing is a continuation of the hearing that the Subcommittee began on April 24, 2013. Today, we will continue the Subcommittee's oversight of how the Centers for Medicare and Medicaid Services pays businesses who supply durable medical equipment such as diabetic testing materials, CPAP machines, back braces, and power wheelchairs to Medicare beneficiaries under Medicare Part B.

During the hearing on April 24, we heard testimony from CMS officials and one of the contractors responsible for conducting oversight of payments for medical equipment.

We invited representatives of two durable medical equipment companies, Med-care Diabetic and Medical Supplies and U.S. Healthcare Supply to provide testimony about their companies' business practices, including how their companies market and promote medical equipment supplies to patients and their doctors.

We also wanted the company representatives to address sample reviews by CMS which show very high error rates and denial rates for durable medical equipment payments made to the companies by the government.

After receiving the Subcommittee's invitation to testify, both individuals, through their attorneys, declined to appear voluntarily before the Subcommittee. Because Ranking Member Johnson and I continue to believe that these companies could provide useful information that would assist the Subcommittee in its oversight of this very important government program, we issued subpoenas to compel their attendance at today's hearing.

I regret that we were forced to use subpoenas to have the opportunity to ask these questions. I believe these witnesses today can

provide important insights about both the operations of their industry and the oversight and performance of the government.

I also welcome the opportunity to have a constructive dialogue about how to make the system more efficient and effective. I look forward to discussing those issues with the witnesses today.

It is the custom of this Subcommittee to swear in all witnesses that appear before us. So, if you do not mind, I would ask you to stand.

Do you swear that the testimony that you will give before this Subcommittee will be the truth, the whole truth, and nothing but the truth so help you, God?

Mr. LETKO. Yes.

Dr. SILVERMAN. Yes.

Senator MCCASKILL. Thank you very much.

Let the record reflect the witnesses have answered in the affirmative.

We will be using a timing system today. We ask that your oral testimony be no more than 5 minutes and your written testimony can be put in the record at whatever length that you would so desire.

The first witness to come before us today is John Letko of U.S. Healthcare Supply LLC.

Mr. Letko, it is my understanding that—let me start with this. What is your company's primary business purpose?

TESTIMONY OF JON LETKO, U.S. HEALTHCARE SUPPLY, LLC

Mr. LETKO. Chairman McCaskill, I would like to answer your question, but based upon the advice of my counsel, I respectfully decline at this time to answer your question based on my Fifth Amendment rights in the Constitution.

Senator MCCASKILL. OK. We respect that right under the Constitution, and we thank you for being here today. We know that your company has been speaking to the press about this issue and we are hopeful that at some point in time your company will be in a position that you could speak to the Committee under oath in the same manner that you are willing to speak to the press about this issue and we thank you for being here today and you are dismissed.

Mr. LETKO. Thank you.

Senator MCCASKILL. The record should reflect that Mr. Letko has availed himself of the privileges afforded under the Fifth Amendment of the Constitution to not give testimony that might incriminate him. The Subcommittee hereby respects that right to decline to answer the questions and the witness has been excused.

[Witness excused.]

We will now go to you, to Mr. Silverman. Mr. Silverman, we appreciate you being here and I am hopeful that we will be able to get a lot of good information out of you today.

Let me start by asking what your role at the company is.

Dr. SILVERMAN. Good afternoon, Madam Chairman. I would like to make an opening statement.

Senator MCCASKILL. I am sorry. Go ahead.

Dr. SILVERMAN. Thank you, ma'am.

Senator MCCASKILL. We are not used to what just happened so I got a little off my script here. So, go ahead and make your statement. I appreciate it.

Dr. SILVERMAN. Thank you, Madam Chairman.

TESTIMONY OF STEVE SILVERMAN, MD, MED-CARE DIABETIC AND MEDICAL SUPPLIES

Dr. SILVERMAN. I welcome the opportunity to be here at this meeting today. My name is Dr. Steve Silverman. I received an AS degree in biology in 1975 from Nassau College in New York. I attended the University of Missouri in Columbia, Missouri from 1975 to 1976. I then graduated from Logan College of Chiropractic in Chesterfield, Missouri in 1979 with a dual degree, a BS in human biology and a Doctor of Chiropractic.

I am licensed in the States of Florida and New York. I started a multi-specialty center in Florida from 1979 to 1998. The name of my practice was American Med-Care Centers, comprised of chiropractors, medical doctors, and exercise physiologists.

We served private insurance as well as Medicare patients. In 1999 I left the practice group to form a medical supply company named Med-Care Diabetic and Medical Supplies Incorporated.

Today, my company has in excess of 435 employees all located in the United States. Medicare represents less than one half of our revenues. We are accredited by the Joint Commission. We are duly licensed in all 50 States and territories and I appreciate the opportunity to be here and look forward to your questions.

Senator MCCASKILL. Thank you very much. You indicated in your opening statement that half of your company's revenues are Medicare?

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. What percentage of the revenues—are any of the revenues attributed to Medicaid?

Dr. SILVERMAN. No. A very small percentage, ma'am.

Senator MCCASKILL. OK. So basically, you are half Medicare and half private pay?

Dr. SILVERMAN. We are also, we have a licensed pharmacy in all 50 States. We have licensed pharmacists and pharmacy techs. So, the other aspect of our income comes through our pharmacies.

Senator MCCASKILL. I see. OK. Do you know what percentage of that might be Medicare D?

Dr. SILVERMAN. No, ma'am.

Senator MCCASKILL. Was that information that you could possibly obtain for the committee?

Dr. SILVERMAN. I am sure I can obtain the information.

Senator MCCASKILL. That would be helpful. Thank you.

And, you may have said this in your opening statement and I missed it. Did you indicate, is this a privately owned company or publicly owned?

Dr. SILVERMAN. It is privately owned, Madam Chairman.

Senator MCCASKILL. What did your company receive in 2012? What was the total amount of money you received from medical equipment supply payments from Medicare in 2012?

Dr. SILVERMAN. To the best of my knowledge, it was approximately $35 million.

Senator MCCASKILL. And, is that average for the last 4 or 5 years? Is that approximately what you received on a consistent basis or is that significantly more than you received in prior years?

Dr. SILVERMAN. It is not significantly more. We have been in business since 1999; and subsequently as years have gone on, our revenues have increased.

Senator MCCASKILL. I want to make sure that you know I would never ask you to provide any information about specific actions that you may or may not be addressing in various inquiries that are being made by other parts of the government, but I am only interested in what actions you have taken in response to the finding by CMS that you had such a high percentage of claims that should have been denied.

In the sample of more than 1,200 claims, they said that 99 percent of them should have been declined and they found, the authors found that over 400 of the more than 590 Medicare claims reviewed were improper and demanded repayment in overpayments. I assume you are aware of these findings.

Dr. SILVERMAN. The first time I became aware of any of the information that you are stating was from your last Subcommittee meeting. I do not know if you are specifically addressing my company.

Senator MCCASKILL. I am.

Dr. SILVERMAN. OK. We have requested information regarding those statements and we have yet to receive it. But may I just state that as a result of what I read from the last meeting, we went back, we are part of the large provider outreach program for CMS. We have in excess of 200,000 patients and CMS has asked us and we voluntarily agreed to work with them. So, we get report cards every quarter from—I was able to go back and review our CERT error rates. From 2010 through most recently of 2012, our error rates were anywhere between 3 and 7.8 percent.

Senator MCCASKILL. So——

Dr. SILVERMAN. Excuse me.

Senator MCCASKILL. Go ahead. I am sorry.

Dr. SILVERMAN. Some of the error rates were based upon equipment that is not paid for by Medicare. In other words, if a patient requested insulin or syringes to treat their diabetes, it is not a covered item from Medicare.

So, we have to submit those claims to Medicare, and those claims then get rejected so that we can bill their other insurance. That is just an example of how some of these claims are attributed to an error rates.

Senator MCCASKILL. OK. So, I am confused. CMS is telling us that your error rate, that when they look closely at reviews, 400 of 590 claims reviewed were improper. And, you are saying that you did not know until the hearing that they had demanded repayment for overpayment on some of those?

Dr. SILVERMAN. To my knowledge, we have not been demanded repayment for overpayment on anything, on any of those items brought up.

Senator MCCASKILL. So, this is really important that you came today because what you are telling me is CMS is telling you to pay

them back and you are saying they never told you to pay them back.

Dr. SILVERMAN. I am not saying that. I do not know—to my knowledge, I have no understanding of CMS asking us to pay back money associated with the review you have mentioned above, and I am not really clear of where the report and what period that report is from. I requested the information. Our attorneys requested to review the information, and I have not been able to review it yet.

Senator MCCASKILL. We certainly can give you all the information that has been part of the public record as part of this hearing, and I can assure you that no one will beat down the door faster at CMS to resolve what appears to be a huge discrepancy in the information that they have provided and the information that you are representing today. They cannot say that you have a gross problem with improper payments and then you not know anything about it.

So, clearly there is a break down here.

Dr. SILVERMAN. I appreciate that and that is one of the reasons I am here today basically just to clear up these issues and not to muddy our name but we work closely with CMS and we would be very happy to go over those results.

And, since 1999 I can tell you that we have had a small minority of audits, never any substantial prepayment audits, and we had actually voluntarily in 2012 given back $750,000 back to CMS.

So, I look forward to working with CMS closely and I would like to clear it up just as quickly as——

Senator MCCASKILL. Well, I can facilitate you getting with CMS I cannot assure you.

Dr. SILVERMAN. Thank you.

Senator MCCASKILL. And we will get to the bottom of it——

Dr. SILVERMAN. OK.

Senator MCCASKILL [continuing]. Because I want to be confident that the problem that is out there which it is a problem in that we have had—and that is why I want to talk about the specifics. I mean, you understand how your company came to light to this Committee?

Dr. SILVERMAN. From the last meeting, yes, Senator.

Senator MCCASKILL. That it was a doctor that contacted us that she was having a great deal of difficulty getting you to stand down in your marketing of these devices to one of her patients.

Dr. SILVERMAN. I would like to comment on that issue if you let me.

Senator MCCASKILL. Absolutely. I am going to ask you some questions about it but go ahead.

Dr. SILVERMAN. Do you want to ask those?

Senator MCCASKILL. No. Go ahead.

Dr. SILVERMAN. Thank you, Senator.

I was able to review the testimony from the physician regarding the claims that her patient were, was cold called basically by our company, and I have empathy toward her in regards to getting many faxes and many paperworks. Many of my friends are physicians and the they would much rather practice medicine than be boggled down with faxes and paperwork.

In this instance, the doctors stated that she was representing her patient and the patient was cold called and the evidence shown was a fax request from our company, Med-Care Diabetic and Medical Supplies, for authorization to give this patient CPAP equipment.

Our policies and procedures regarding advertising, basically we advertise on a website and web health sites. Every one of our advertising basically has a box that a patient must check that essentially gives express written permission for our company, Med-Care Diabetic and Medical Supplies, to call them.

In this particular instance with this physician's patient, we have documentation showing express written permission from this patient to allow our staff to call them.

So, No. 1——

Senator MCCASKILL. Do you know where—this is Mrs. Pariseau?

Dr. SILVERMAN. Ah. Can I mention names?

Senator MCCASKILL. Sure. Her letters and faxes and her information.

Dr. SILVERMAN. Dr. Kennedy's patient, and I just want to be respectful of any Health Insurance Portability and Accountability Act (HIPAA) guidelines so. Dr. Kennedy's patient was not Mrs. Pariseau, and also I would like to add that Dr. Kennedy's patient—— [Pause.]

Senator MCCASKILL. OK. I want to make sure you see these. Did you get copies of the letters that I am referring to?

Dr. SILVERMAN. I have a copy of Dr. Kennedy's letter to you.

Senator MCCASKILL. Right.

Dr. SILVERMAN. I just want to also state regarding this patient, this patient did not have Medicare benefits. Her benefits were actually United Healthcare, which is a private insurance.

Senator MCCASKILL. OK.

Dr. SILVERMAN. So in this instance, Dr. Kennedy is basically stating the patient did not request any of these devices or products, but we have expressed written permission from this patient for our office to contact her.

They were not cold calls, and the only other evidence that was presented was a prescription faxed to Dr. Kennedy where she had said that the patient did not require a CPAP machine because they already had one.

At this point, we did not further contact the patient. And, the patient was not contacted again. We did not contact Dr. Kennedy after this. The patient was never billed, shipped supplies.

Senator MCCASKILL. OK. So, let me back up about the written consent. So, you are saying you are not calling patients until you have expressed written consent?

Dr. SILVERMAN. Yes, ma'am. Our program has been reviewed and approved by CMS.

Senator MCCASKILL. And, is the written consent in the form most times of somebody checking a box on an Internet ad?

Dr. SILVERMAN. The written consent on our website shows that the patient, we explain our privacy policy to the patient and we also explain the fact that the patient is agreeing to be called Med-Care.

Senator MCCASKILL. Tell me exactly how they get there. Say it is my elderly aunt, and she is looking up something about her diabetes, and she sees an ad on that page, and she clicks on that ad. It says you can get free testing equipment.

Dr. SILVERMAN. We do not ever state anything free.

Senator MCCASKILL. OK. You can get testing equipment at little or no cost to you.

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. I think that is the phrase that is most frequently used.

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. Little or no cost to you, and you click on that box. And, then where does she go?

Dr. SILVERMAN. She immediately gets an e-mail from our company, and the e-mail basically——

Senator MCCASKILL. Without her entering in her e-mail address she gets an e-mail from you?

Dr. SILVERMAN. No, I am sorry, Ma'am. On our website, we have——

Senator MCCASKILL. So, she clicks through and she gets to your website.

Dr. SILVERMAN. Yes. There is a place on the website.

Senator MCCASKILL. And, she has to fill in her e-mail address.

Dr. SILVERMAN. Her name, her e-mail address, and her telephone number——

Senator MCCASKILL. So, the woman who——

Dr. SILVERMAN [continuing]. Then there is a box that she needs to check that she is giving us express written permission to contact, and those are the CMS guidelines.

Senator MCCASKILL. OK. And, are there any that you are calling that you are giving some way other than that visit to your website?

Dr. SILVERMAN. No, ma'am.

Senator MCCASKILL. So, you do not have any other methods. So, if someone does not have a computer and they are saying that they got a call from you and you had a doctor's name, you had their named, and you said that you were Med-Care and they thought you meant Medicare because your name sounds just like Medicare, you do not think that is really happening?

Dr. SILVERMAN. No, ma'am. First of all, we do not present ourselves as Medicare.

Senator MCCASKILL. Why did you name yourself that then?

Dr. SILVERMAN. My medical office was named American Med-Care Centers; and when I left that office, that name was still in use. So, I just abbreviated it to Med-Care Diabetic and Medical Supplies.

Senator MCCASKILL. And, it is just a convenience or a coincidence that when someone calls and says this is blah blah blah from Med-Care that elderly people just might accidentally think they are talking to Medicare.

Dr. SILVERMAN. We do not present ourselves that way.

Senator MCCASKILL. So, do they say we are not Medicare?

Dr. SILVERMAN. We say we are Med-Care Diabetic and Medical Supplies; and if a patient were to ask, are you Medicare, of course, we say no, we are not Medicare.

Senator MCCASKILL. OK. Do you have any contracts with third parties to get phone numbers, call lists, or information about Medicare beneficiaries?

Dr. SILVERMAN. No, ma'am.

Senator MCCASKILL. And, you are not buying lists from anyone?

Dr. SILVERMAN. No, ma'am.

Senator MCCASKILL. OK.

Dr. SILVERMAN. Our advertising is purely web-based; and like I said, the Joint Commission and CMS has reviewed it and has approved it.

Senator MCCASKILL. OK. Have you been investigated for violating this prohibition on direct marketing?

Dr. SILVERMAN. In terms of investigated by whom?

Senator MCCASKILL. By CMS.

Dr. SILVERMAN. We had a corrective action procedure this past fall. Our advertising, CMS had done their yearly inspections last summer and we had given them copies of our advertising.

In a couple of our advertisements, the patient request to be contacted was in our privacy policy. So, CMS reviewed this and they essentially wanted us to be more clear about where it was.

So, there were a few ads that, like I said, were in the privacy policy and we corrected that. CMS, it was called a corrective action procedure. CMS approved it. They reviewed all of our advertising and——

Senator MCCASKILL. So, now do you have to check two boxes? One that you understand the privacy policy and one you are willing to be contacted?

Dr. SILVERMAN. No, just the willing to be contacted. Our privacy policy is in regards to HIPAA, and we want our patients to understand that their patient information is protected.

Senator MCCASKILL. OK. So, the only action they can take is clearly delineated now "I am willing to be contacted by your company?"

Dr. SILVERMAN. Yes. And, CMS, just getting back to CMS, we were retroactively approved. We never lost any billing. We never lost any licensure. They just wanted clarification; and unfortunately, it was over Christmas. So, it took a little bit of a period of time but, it was fine.

That is the only actions that my company has had, and I have been billing Medicare since I started out in practice since 1979 without major incident.

Senator MCCASKILL. So, I am back to Mrs. Pariseau. She claims that you called her and that she had no idea what was going on and that she did not understand that she was talking to a company and that she thought it was Medicare because you had all of her information.

She indicated she never asked for a prescription and yet she is getting a letter that says our sleep apnea prescriptions have been approved.

Dr. SILVERMAN. In this particular instance, Senator McCaskill, I was also able to go back to our records and we have a form, a document that basically has shown that Mrs. Pariseau has given us express written permission to contact.

Senator MCCASKILL. And, how did you get that.

Dr. SILVERMAN. She apparently went on a website and filled out that document.

Senator MCCASKILL. Will you share those documents with us?

Dr. SILVERMAN. Absolutely.

Senator MCCASKILL. OK. So, I would like to see where Mrs. Pariseau gave you permission, and where did you get her phone number?

Dr. SILVERMAN. On the website, the patient fills out her name, her e-mail address, her phone number.

Senator MCCASKILL. So, she gave you her phone number on a website.

Dr. SILVERMAN. Yes, ma'am, and that is why when we contact them, again just to talk about our current marketing, the patient gets an e-mail right away; and if they do not want to be contacted, they had the right to be put on a do not call list and we do not contact.

Senator MCCASKILL. What if she does not respond to your e-mail? Do you send her a letter?

Dr. SILVERMAN. No. We contact her by phone; and then at that point in time, if the patient has any confusion, the patient says I did not fill this out, I do not want the supplies, then we apologize. We tell them we are sorry we bothered them, and no further actions are taken.

Senator MCCASKILL. OK. So, in this instance, you are saying Mrs. Pariseau went on your website, she filled in her e-mail address, she filled in her phone number, and then you send her an e-mail.

Did she respond to your e-mail or not respond to your e-mail?

Dr. SILVERMAN. No. We contacted the patient and then we sent out prescriptions requests.

Senator MCCASKILL. Wait. I want to know how you contacted her. You are saying the first thing she did is she went on your website and she gave you all this personal information.

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. Then, you are saying that you contacted her. Did you contact her by e-mail first?

Dr. SILVERMAN. No, ma'am, by phone.

Senator MCCASKILL. OK. So, you did not e-mail her. I thought you just said you always e-mailed them.

Dr. SILVERMAN. It is the policy of our office to e-mail. In this particular instance, I would think that, according to our office policy, we would have e-mailed her. I have no e-mail back from her so I do not have any documentation to show you.

But our next procedure, once we receive the documentation that allows us to call, we then call the patient and speak with the patient and we get their insurance information from the phone call. We ask them about the type of supplies they are desiring and we get the physician information so we can contact the physician for a prescription for that item.

Senator MCCASKILL. OK. So, in this instance, you did not, you do not know whether you e-mailed her or not but you know that you called her.

Do you know for sure whether you e-mailed Mrs. Pariseau or not?

Dr. SILVERMAN. I do not know for sure.

Senator MCCASKILL. So, you are saying the policy would be that you would e-mail her; and that if she does not respond to your e-mail, then you call her?

Dr. SILVERMAN. No, ma'am. The express policy of our office is if the patient gives us permission to contact them, we call them on the phone.

Senator MCCASKILL. Oh, OK. So, the e-mail is superfluous to the policy. The policy is——

Dr. SILVERMAN. The e-mail is another fail-safe method that we actually put in place to protect citizens and to protect their rights so as not to bother them.

But if a patient gives us express permission to call them, then we call them; and if there are any issues at that time, we resolve the issues; and if the patient does not want us to followup with a physician's request for supplies, we do not send out a physician's request.

Senator MCCASKILL. And, I want to apologize to you because I should have spent sometime on your website and I should have already seen all of this and I wish I had of because I would be much better at questioning you now had I.

But does it expressly say on the website, you can call me?

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. OK.

Dr. SILVERMAN. It says——

Senator MCCASKILL. So, they know when they are filling in their phone number that they are asking for you to call them?

Dr. SILVERMAN. Yes. Yes, ma'am.

Senator MCCASKILL. OK.

Dr. SILVERMAN. Yes, Senator.

Senator MCCASKILL. So, Mrs. Pariseau, according to you, filled in this website, gave her phone number, but she did not give her doctor's name or her prescription, did she?

Dr. SILVERMAN. Yes, Senator, she gave——

Senator MCCASKILL. On the website?

Dr. SILVERMAN. Not on the website. Once the patient——

Senator MCCASKILL. Well, I am still at the website.

Dr. SILVERMAN. The patient basically grants us expressed permission to call them.

Senator MCCASKILL. OK. Now, she says when you called her, you already knew our name, her prescriptions, and her doctor. Is she mistaken?

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. So, that is not true.

Dr. SILVERMAN. To my knowledge, I can——

Senator MCCASKILL. Would there be any way your company would have her name, her prescriptions, and her doctor before you talk to her?

Dr. SILVERMAN. No, ma'am.

Senator MCCASKILL. OK.

Dr. SILVERMAN. We have all this——

Senator MCCASKILL. So, you understand from her perspective you called her, you said you were Med-Care, you knew her doctor, you knew her prescription, this is what she is telling us.

You knew her doctor, you knew her prescriptions, and then she started getting letters that she needed to sign off on her getting her new sleep apnea machine.

Dr. SILVERMAN. I would like to explain to you, because if that is this woman's perception, that is her perception. But I would like to explain to you our policies and procedures.

In this instance, her perception is incorrect. Based upon her requesting information for us to contact her, we then will phone her; and at that point, we would get her physician information. We would get her insurance information; and at that point if she did not want any further contact from our company or if she had misconceptions of who we were, we would have straightened it out right then and there.

But in this particular instance, we were given the name of her physician and then we contacted her physician. We then sent the patient a new patient letter which, again from our perspective, introduces our company, introduces our procedures, and again tells the patient that no further action is taken in the future unless we speak to them again.

So, we sent out the new patient letter; and from the last hearing, you basically attributed that to aggressive sales advertising. But from my perspective, it is good patient management and care because it is another way of explaining the program to the patient. It is another way of the patient not going forward with the program if they want to opt out.

Senator MCCASKILL. I appreciate that, Dr. Silverman. I do.

Dr. SILVERMAN. Thank you.

Senator MCCASKILL. I am coming at this from the perspective of the Medicare patient who is complaining to Congress that she was aggressively marketed in a way that made her uncomfortable, that she did not understand how this happened or why it happened and that this is a problem. I guess——

Dr. SILVERMAN. Thank you for allowing me to explain that.

Senator MCCASKILL. From your perspective, I get that that is what you think occurred. I——

Dr. SILVERMAN. And again, Senator, we have——

Senator MCCASKILL. Is it possible that any of your people working for your company, are they compensated based on how much they sell?

Dr. SILVERMAN. No, ma'am.

Senator MCCASKILL. There is no commissions?

Dr. SILVERMAN. They are a salaried employee.

Senator MCCASKILL. No commissions?

Dr. SILVERMAN. They——

Senator MCCASKILL. I want to make sure. You are saying that everybody at your company makes the same amount no matter how many machines——

Dr. SILVERMAN. No, ma'am.

Senator MCCASKILL [continuing]. They sell.

Dr. SILVERMAN. They have incentives, yes.

Senator MCCASKILL. OK. And, the incentives are based on how many machines they sell.

Dr. SILVERMAN. Not necessarily machines. There is no monetary basis but it is based upon who they speak to and how many orders they get.

Senator MCCASKILL. OK. So, it is based on how many orders they get?

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. And, the orders are for machines. They are for braces or they are for apnea or for diabetic testing. I mean, let us not mince words here. You get compensated more money if you sell more.

Dr. SILVERMAN. We are an equal opportunity employer.

Senator MCCASKILL. Of course. I get that and I am not——

Dr. SILVERMAN. But it is——

Senator MCCASKILL. Listen. The government set up a system here that allowed what I think at one point people believed it would be a free market of competition that would drive costs down. It turns out without competitive bidding and a free-for-all among seniors in terms of marketing that it did not work out that way.

So now, we are trying to put the cow back in the barn in a way that protects legitimate businesses that have this equipment that they want to sell and have a right to make a profit.

Dr. SILVERMAN. Yes.

Senator MCCASKILL. But I guess when we revised, when the regulations were revised on direct marketing that prohibited in-person contacts, when they tried to revise them to include e-mails and instant messaging, do you understand that perhaps those changes might be necessary?

Dr. SILVERMAN. I follow all the standards and rules. I do not make the rules. But believe me, based upon my past and I am very aware of consumer, protecting the consumer but regarding the rules and regulations, we are regulated, we are inspected, and whatever the rules and regulations are there I give our best effort for myself and all my employees to follow them.

Senator MCCASKILL. And I appreciate that. I guess I am asking you about changing the rules. Do you see a benefit other than, I mean, this is kind of mean because I am asking you, are you OK with the rule that is going to allow you to sell less because if you are worried about selling more this is not going to help you.

Dr. SILVERMAN. I am not worried about selling more. I want to play by the rules.

Senator MCCASKILL. OK. Well, if you are not worried about selling more, do you understand that it seems, I think, a little weird that you would try to, even if someone clicked, believe me, my mother who I miss very much click a lot of things on the Internet she should not have clicked.

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. She gave out a lot of information that she should not have given. I kept saying, mom, bridge, play bridge. E-mail your grandchildren.

With a senior population, do not you think if they need medical equipment, it should come from their doctor and not from a go-between between the patient and the doctor that is contacting the patient directly even if you are actually following the rules that allows you, for purposes of this hypothetical, assuming every single

person you call is somebody who has given you their phone number and their name and their e-mail on your website——

Dr. SILVERMAN. Yes.

Senator MCCASKILL [continuing]. Every single phone call that you make is attributable to that, assuming that that is correct, and I got to tell you that is a hard assumption for me to make but I am going to make it out of deference to your testimony.

Dr. SILVERMAN. I have documentation.

Senator MCCASKILL. Do you understand that it seems from this side of the table that it would make a lot more sense for that marketing to go on to the doctor as to the efficacy of your equipment, the reliability and efficiency of your company, your customer service, and that the doctor should be the only one making the decision or requesting that the patient gets the equipment?

Dr. SILVERMAN. I have been a physician for many years so I can talk to the you from both sides from an office standpoint, and I still think that patients do have rights to choose who they want to get services from.

Sometimes patients are intimidated by their physician. They do not agree with their physician. They do other things. So, I think primarily a patient has the right to choose.

As far as——

Senator MCCASKILL. Do you think that these seniors, though, are making knowing choices? You know the ones——

Dr. SILVERMAN. I——

Senator MCCASKILL. Do you think when my mom ended up with five diabetic testing machines, you think that is because she needed five.

Dr. SILVERMAN. We have——

Senator MCCASKILL. Or do you think it was because she kept getting contacted because the company had her as a patient before and they had the right to contact her again and say, hey, we have a new and improved model we can send you out at little or no cost to you——

Dr. SILVERMAN. I do not——

Senator MCCASKILL [continuing]. Which read underneath that means the Federal Government is going to pay for it?

Dr. SILVERMAN. I do know that everything we do is based upon signed prescriptions from physicians. So, the physicians are basically telling their patients that they can go and utilize our services. So that is that from that perspective.

Going back to your original question regarding physicians, I do not know if a physician can efficiently offer all these medical devices to their patients. It is an industry that is very regulated. It is an industry that requires a lot of work, and physicians are busy treating their patients. So——

Senator MCCASKILL. No, I do not mean them provide it. I mean that they are the ones that contact you and Pariseau's doctor would call, A member of my family got a sleep apnea machine. It did not happen because somebody, he did not click a website.

The member of my family that got it, you know, what happened? He went to the doctor. He had a sleep test, and the doctor said, I am going to prescribe you this machine and here is three choices you have of the equipment. Here is the relative pros and cons of

each kind of the equipment, and you can call all three of these companies and they will talk to you about their equipment or you can pick one. That is completely up to you but you need this machine.

It was not that he had gone on a website and clicked and put in his phone number and then gotten a call and said at little or no cost to you, we are going to run this fax to your doctor's office and see if we can get them to sign off and you are good to go.

Dr. SILVERMAN. I understand; but again if the doctor did not want that patient to utilize our services and supplies, they just would not sign that prescription.

Senator MCCASKILL. So maybe, do you think if we are going to try to tighten it up that we need to begin at the doctor's office and give them some kind of disincentive to sign off on these prescriptions without actually looking at the files and discussing it with the patient?

Dr. SILVERMAN. I am not a policymaker.

Senator MCCASKILL. Well, maybe that is the answer. Maybe we stop it there. Does your company have a surety bond?

Dr. SILVERMAN. Yes, ma'am.

Senator MCCASKILL. Tell me what you think about——

Dr. SILVERMAN. I am sorry. Regarding this patient, we actually have prescriptions signed from the physician saying the patient can get services from our company.

Senator MCCASKILL. Was that before or after you sent her the letters?

Dr. SILVERMAN. At the same time. We sent out a new patient letter and we request a prescription from the physician. So, we have physician authorization to treat this patient.

What happened in this particular instance, to be perfectly honest and blunt with you, the physician's prescription was not filled out correctly. The physician did not date the prescription.

So, we were not able to supply this patient with their supplies, and we had contacted the physician's office telling——

Senator MCCASKILL. It was a good thing because they did not want it.

Dr. SILVERMAN. Well, in that case, what happened was, based upon the fact that the physician did not fill out the prescription, there was somewhat of a time lag and then we contacted the patient. At that point, the patient said that she decided to stay with her original provider, and that is essentially what happened in this case.

Senator MCCASKILL. OK. Well, we will go back and obviously I want to see the documentation from your end on this and we will go back and analyze this case. Obviously, this is one case out of, we have a lot of people that contacted our office.

Dr. SILVERMAN. Yes, ma'am, and that being said, I would like you to speak to counsel regarding releasing the information that you are requesting.

Senator MCCASKILL. Well, how about, I think that is fine if I get the permission of the patient.

Dr. SILVERMAN. Yes.

Senator MCCASKILL. Obviously, I do not think you have any HIPAA concerns if I have the permission of the patient.

Dr. SILVERMAN. I have no——

Senator MCCASKILL. She contacted us. We did not——

Dr. SILVERMAN. As long as we are compliant, Senator, I have no concerns.

Senator MCCASKILL. OK. Tell me what you think about the competitive bidding program.

Dr. SILVERMAN. Excuse me, Senator. [Pause.]

I would very much like to answer your question regarding competitive bidding but just for your information also when you request documents, we have a patient comment report that is dated that has all the comments from the patient.

Senator MCCASKILL. Great. We will look forward to seeing that.

Dr. SILVERMAN. OK. My opinion on competitive bidding is I am in favor of competitive bidding. I have some concerns based upon the pricing. I have some concerns based upon the capacity.

I think that for diabetic patients, there are 25 million diabetic patients in the country and competitive bid contracts were awarded to only 10 to 15 providers.

Senator MCCASKILL. As compared to how many providers are out there now?

Dr. SILVERMAN. I do not know the exact number of providers but there are thousands and thousands. At one point there were 50,000 providers, and the CMS has done its job, and its policies have gotten rid of a lot of the providers in that who were not doing the job properly.

But there is an estimate that maybe there will be a thousand providers to participate in competitive bidding; and out of the thousand, 10 to 15 providers will be able to help people requiring diabetic testing supplies.

So, in this instance, that chosen provider is going to need a large capacity office to really provide these seniors with product, and I fear that there will be confusion. I fear that seniors will not know where to turn. I fear that they will not be able to test, and it is well documented that if patients do not test themselves, their disease can get worse. The medical bills skyrocket. That is my concern.

Senator MCCASKILL. And, I appreciate; and one of the reasons that I am trying to work in this area is because I think it is ripe for confusion, and I think the current system allows a lot of that also.

I think that is one of the reasons why we had so many people contact our office on this subject. When asked if they have been solicited for medical equipment directly, we got a lot of people that stepped up and those are the ones that are paying attention to what is being said in the news or on TV about Congress.

And frankly, most people right now in America just hope we go away. So, the fact that we had a lot, that is from a pretty small universe because there is a lot of people out there for a lot of good reasons who are not paying much attention to us.

Dr. SILVERMAN. I appreciate you protecting the consumer and it is my job too to do the right thing.

Senator MCCASKILL. And the Treasury both, I mean, because both of them are having lots of people trying to sell them equipment, while it is disruptive and confusing to seniors, what it really is is expensive for the Medicare program.

Dr. SILVERMAN. I think that is the answer with competitive bidding. I just hope that it will be efficient and not cause more confusion to seniors.

Senator MCCASKILL. Does Mr. Porush have any relationship with Med-Care at the current time?

Dr. SILVERMAN. Yes. Mr. Porush is an employee, not an owner, a Med-Care Diabetic and Medical Supplies.

Senator MCCASKILL. OK. Is he a consultant or an employee?

Dr. SILVERMAN. He is an employee.

Senator MCCASKILL. And, how long has he been an employee?

Dr. SILVERMAN. He has been an employee since 2004.

Senator MCCASKILL. OK. Is the information that was contained in the Forbes article about Mr. Porush and Florida residents complaining about your company's sales tactics including cold calling Medicare recipients to persuade them to order diabetic supplies, did that pre-date the regulations that do not allow cold calling, the cold calling complaints that were written about in the Forbes article?

Dr. SILVERMAN. I do not know. But the Forbes article in my opinion, is not true.

Senator MCCASKILL. OK. So, was there a time that your company did do cold calling?

Dr. SILVERMAN. To my knowledge, no.

Senator MCCASKILL. OK. We deeply appreciate you being here, and I will make sure that we get you information that you want from us that is part of the public record. There may be some information CMS has given us that we have used to prepare for this hearing that we are not at liberty to give you and vice versa.

We would appreciate any documentation you can give us. In fact, we would provide to you some of the names of the people that complained about being contacted by your company when they do not believe they had ever given you permission to contact them and we would appreciate you providing us the documentation that they had given you the express authorization to contact them.

Dr. SILVERMAN. Yes, Senator.

Senator MCCASKILL. How would it change your business model if you could no longer get people to give you their phone numbers on a website?

Dr. SILVERMAN. We would no longer do that. So, I am sure——

Senator MCCASKILL. What percentage of your business comes from the calls you make to seniors from the numbers on your website?

Dr. SILVERMAN. Well, I do not have those numbers.

Senator MCCASKILL. But you could get them.

Dr. SILVERMAN. Yes, ma'am. But also I would like to state again that less than half of our revenues are from seniors.

Senator MCCASKILL. No, I am not talking about within the Medicare space.

Dr. SILVERMAN. Yes.

Senator MCCASKILL. I mean frankly the prescription stuff, that is another hearing for another day. You can look forward to that, Dr. Silverman. We will get there.

Dr. SILVERMAN. I would be happy.

Senator MCCASKILL. I am on a mission. We are going to bring down these health care costs in a way that is not harmful to seniors. If we can do it at all, we are going to try to do it because Medicare is going to bust this country if we are not careful. We cannot afford to be running the Medicare program the way it has been run.

Dr. SILVERMAN. I appreciate the opportunity for you to allow me to explain some of the misconceptions from the last meeting and clear up our name.

Senator MCCASKILL. Well, what I would like is to find out of the Federal Government stream of money, the 35 million last year, what percentage of that came from you being contacted by a doctor versus you contacting a patient.

Dr. SILVERMAN. OK. If I can provide that information to you, I will be happy to.

Senator MCCASKILL. I bet you have it because it is going to be very hard for you to give incentives if people cannot prove that they were the ones that actually moved the product, and so I am betting you have it internally, and it would be very helpful for us to see what percentage of your business is coming from the contact to seniors.

And, do you believe if we took that away, if we change the rule and said, you cannot call patients directly, you can only, they can only receive their prescriptions through recommendation of their doctors——

Dr. SILVERMAN. Well, I think competitive bidding is the answer to that right now.

Senator MCCASKILL. Because you are not going to advertise anymore because it is not going to be——

Dr. SILVERMAN. Well, it is a capacity issue. With competitive bidding, we are going to be busy enough just trying to deal with capacity so.

Senator MCCASKILL. Are you going to be one of the participants?

Dr. SILVERMAN. We look forward to participating.

Senator MCCASKILL. And so, have you been awarded?

Dr. SILVERMAN. At this present time, we are waiting approval and our bid is being reviewed. So, we look forward to participating.

Senator MCCASKILL. Then, you would be part of the 93 cities that are going to be rolled out this summer?

Dr. SILVERMAN. Yes, and I think we have the capacity. Because of our large facility and the amount of employees, I think we are a perfect candidate to make this program successful.

Senator MCCASKILL. Well, then, we probably will not see the last of you then. You can look forward to more appearances in front of this Committee. I know you cannot wait.

Dr. SILVERMAN. I am becoming comfortable.

Senator MCCASKILL. Thank you, Dr. Silverman.

Dr. SILVERMAN. Thank you, Senator.

Senator MCCASKILL. The hearing is adjourned.

[Whereupon, at 2:50 p.m., the Subcommittee was adjourned.]

APPENDIX

STATEMENT OF

PETER BUDETTI, M.D., J.D.
DEPUTY ADMINISTRATOR AND DIRECTOR,
CENTER FOR PROGRAM INTEGRITY,
CENTERS FOR MEDICARE & MEDICAID SERVICES

AND

LAURENCE D. WILSON
DIRECTOR
CHRONIC CARE POLICY GROUP, CENTER FOR MEDICARE
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

"OVERSIGHT AND BUSINESS PRACTICES OF DURABLE MEDICAL EQUIPMENT COMPANIES"

BEFORE THE

U. S. SENATE COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS, SUBCOMMITTEE ON FINANCIAL AND CONTRACTING OVERSIGHT

APRIL 24, 2013

U.S. Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Financial and Contracting Oversight

Oversight and Business Practices of Durable Medical Equipment Companies

April 24, 2013

Chairman McCaskill, Ranking Member Johnson, and Members of the Subcommittee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to reduce wasteful spending for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Thanks to an aggressive and multifaceted strategy to address DMEPOS fraud, waste, and abuse, per-capita DME spending has declined almost 10 percent from 2008 to 2011 without any loss of access of quality for Medicare beneficiaries.[1] Total DME spending has also decreased; in 2011, Medicare DME spending totaled $7.8 billion, down 6 percent from $8.3 billion in 2008.[2] CMS is pursuing a comprehensive strategy to further reduce the fraud, waste and abuse that result in improper payments by reimbursing suppliers at market rates through the DMEPOS competitive bidding program; preventing improper expenditures through the Power Mobility Device (PMD) prior authorization demonstration; screening DMEPOS suppliers to root out bad actors; and a program integrity strategy centered on prevention and partnering with law enforcement. Through these initiatives and new tools provided by the Affordable Care Act, CMS is working to ensure the sustainability of the Medicare Trust Funds and protect beneficiaries who depend upon the Medicare program's DMEPOS benefit.

Background

CMS is the largest purchaser of health care in the United States, and each year the Medicare program, beneficiaries, and taxpayers spend billions of dollars for DMEPOS for millions of Medicare beneficiaries. Yet, the current Medicare DMEPOS benefit is plagued by an obsolete fee schedule methodology, grossly inflated prices, and a well-documented proliferation of fraudulent practices fueled by these inflated prices. With the exception of the nine areas in Round 1 of the program where competitive bidding is now in effect, CMS is statutorily required

[1] See "HRR Table – All Beneficiaries," available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/index.html

[2] See "HRR Table – All Beneficiaries," available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/index.html

to pay for DMEPOS items and services using fee schedule rates for DMEPOS items in Medicare Part B. In general, the statute requires that fee schedule rates are calculated using historical supplier charge data from more than 20 years ago that are often much higher than current market prices. As a result, Medicare payment rates are often higher than the prices paid by non-Medicare customers for identical items and services. Medicare beneficiaries and taxpayers bear the cost of these inflated fee schedule rates. The Department of Health and Human Services' Office of Inspector General (OIG), the Government Accountability Office (GAO), and other independent analysts have repeatedly warned that the fee schedule prices paid by Medicare for many DMEPOS items are excessive, as much as three or four times the retail prices and amounts paid by commercial insurers or customers who purchase these items on their own. These inflated prices in turn increase the amount beneficiaries must pay out-of-pocket for these items in the form of deductibles, co-insurance, and premiums and help fuel the well-documented proliferation of DMEPOS fraud, waste, and abuse. For example, CMS noted in a 2011 report[3] that over 80 percent of claims for power mobility devices in the Medicare fee-for-service program, representing approximately $492 million, did not meet Medicare coverage requirements.

DMEPOS Competitive Bidding Program

The DMEPOS competitive bidding program is one of the most powerful tools in CMS' arsenal to reduce DMEPOS spending and provide greater value to the Medicare program, beneficiaries and taxpayers. It is projected to save the Medicare Part B Trust Fund $25.8 billion and beneficiaries $17.2 billion over ten years.[4] The program works by establishing Medicare's DMEPOS payments based on competitive market pricing, thereby reducing beneficiary out-of-pocket costs, program outlays, and suppliers' incentive to fraudulently bill Medicare for DMEPOS. This year, building on the program's initial successes, CMS will expand DMEPOS competitive bidding from nine initial sites in the Round 1 Rebid to an additional 91 metropolitan areas for Round 2. Moreover, prices for diabetic testing supplies nationwide will be set based on a national mail-order competition.

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[3] Medicare Fee-for-Service 2011 Improper Payments Report, available at http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Downloads/MedicareFFS2011CERTReport.pdf

[4] FY 2014 Congressional Justification, Page 38. Available at http://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2014-CJ-Final.pdf

Congress established the Medicare DMEPOS Competitive Bidding Program in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173). The program was modeled after the successful demonstration projects in Polk County, Florida and San Antonio, Texas between 1999 and 2002, which resulted in 20 percent savings for Medicare and beneficiaries without any negative impact on access to equipment or quality of care for beneficiaries. Under the MMA, the DMEPOS Competitive Bidding Program was to be phased into Medicare so that competition under the program would initially begin in 10 metropolitan statistical areas (MSAs) in 2007. Consistent with the statutory mandate, CMS conducted the Round 1 competition in 10 areas and for 10 DMEPOS product categories, and implemented the program on July 1, 2008. However, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275) delayed the start of the program. MIPPA terminated the Round 1 contracts that were in effect and reinstated fee schedule payment rates, required rebidding of the first round at a later date, and imposed a nationwide 9.5 percent payment reduction for all Round 1 items in 2009.

CMS implemented the Round 1 Rebid of the competitive bidding program in nine MSAs on January 1, 2011, covering nine DMEPOS product categories and awarding 1,217 DMEPOS competitive bidding program contracts to 356 suppliers. All contract suppliers were thoroughly vetted during bid evaluation to ensure that they were in good standing with Medicare and met Medicare enrollment rules, quality and financial standards, and accreditation and state licensure requirements. CMS also screened and evaluated all bids to ensure that they were bona fide and based on real supplier costs. Only qualified bidders with bona fide bids were offered contracts. The bid evaluation process ensured that there would be more than enough suppliers, including small business suppliers, to meet the needs of the beneficiaries living in the competitive bidding areas (CBAs). Approximately 51 percent of the winning suppliers from the Round 1 Rebid are small business suppliers, well exceeding the 30 percent goal established by CMS. Ninety-two percent of suppliers that were offered a contract accepted the contract terms.

CMS has closely monitored the results of the competitive bidding program since implementation to ensure that savings goals of the program have been achieved and – more importantly – to

ensure that beneficiary access to appropriate supplies and equipment has not been compromised. To ensure effective monitoring, CMS implemented a real-time claims monitoring system which analyzes the utilization of the nine product categories. CMS' claims monitoring system was designed to pay particular attention to potential changes in key secondary indicators such as hospital admissions, emergency room visits, physician visits, and admissions to skilled nursing facilities before and after the implementation of the new payment model. For the first year of the program, CMS' real-time claims monitoring and subsequent follow-up has indicated that beneficiary access to all necessary and appropriate items and supplies has been preserved in the nine CBAs.

Moreover, CMS' monitoring revealed the competitive bidding program may have curbed previous inappropriate distribution of these supplies. For example, when CMS' monitoring showed declines in the use of mail-order diabetes test strips and Continuous Positive Airway Pressure (CPAP) supplies in the CBAs, CMS initiated three rounds of outbound phone calls to users of these supplies in the nine CBAs: two rounds of calls for users of mail-order diabetes test strips and one round of calls to users of CPAP supplies. In each round, CMS staff randomly identified 100 beneficiaries who used the items before the program began but had no claims for the items in 2011. The calls revealed that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, which would suggest that beneficiaries had historically received excessive replacement supplies before they were medically necessary.

The DME competitive bidding program is already generating significant savings for the Federal government and the approximately 2.3 million Medicare fee-for-service beneficiaries residing in the areas where competitive bidding is in effect. According to CMS's analysis of claims from 2010 and 2011, the competitive bidding program has reduced DMEPOS spending by approximately $202.1 million—or 42 percent overall—in the nine Round 1 Rebid areas.[5] The program has significantly reduced payment amounts, with an average price reduction of 35 percent from the fee schedule. For example, if Medicare suppliers in the nine CBAs had instead

[5] Competitive Bidding Update—One Year Implementation Update, available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf

been paid the 2011 Medicare fee-schedule amounts, Medicare suppliers would have been paid $173.31 per month for stationary oxygen equipment (e.g., oxygen concentrators), of which the beneficiary would have paid 20 percent in cost-sharing. (The supplier would have received $2,079.72 over the course of the year, of which the beneficiary would have paid $415.94 in cost-sharing.) Under the competitive bidding program, the average Medicare allowed monthly payment amount for stationary oxygen equipment in the nine competitive bidding areas has been reduced by 33 percent from $173.31 to $116.16. Further, a beneficiary's cost-sharing responsibility for stationary oxygen equipment rental for a year has been reduced by an average of $137 in the nine areas.

Building on the success of the Round 1 Rebid, CMS announced in August 2011 the expansion of the competitive bidding program, as required by MIPPA and the Affordable Care Act,[6] to 91 additional areas for Round 2. In addition to the items included in the Round 1 Rebid, CMS expanded the list of items bid by combining standard manual wheelchairs, standard power wheelchairs, and scooters to form a new expanded standard mobility device product category; expanded bidding for support surfaces throughout all Round 2 areas; and added negative pressure wound therapy pumps and related supplies and accessories as an additional product category. CMS also conducted a national mail-order competition for diabetic testing supplies at the same time as Round 2. The national mail-order competition includes all 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa.

On January 30, 2013, CMS announced the new payment rates for the eight product categories included in Round 2 of the DMEPOS competitive bidding program—prices that are, on average, 45 percent less than Medicare's current fee schedule amounts, and 72 percent less for mail-order diabetic supplies. As with Round 1 of the program, competitive bidding will yield significant savings for Medicare, beneficiaries, and taxpayers. For example, Medicare suppliers are currently paid based on fee schedule amounts that average $77.90 per month for mail-order diabetic testing supplies (100 lancets and test strips), of which the beneficiary pays 20 percent

[6] MIPPA required competition for Round 2 of the program to be conducted in 2011 in 70 additional MSAs. The Affordable Care Act (P.L. 111-148 and P.L. 111-152) subsequently expanded the number of Round 2 MSAs from 70 to 91 and mandates that all areas of the country be subject either to DMEPOS competitive bidding or payment rate adjustments to the fee schedule using competitively bid rates by 2016.

(approximately $15.58 per month on average). Under the competitive bidding program, the average Medicare allowed monthly payment amount for these supplies will be reduced from $77.90 to a national rate of $22.47.

CMS announced 13,126 Round 2 DMEPOS competitive bidding contracts to 799 suppliers, as well as contracts to 18 mail-order diabetic testing suppliers, on April 9, 2013. As in Round 1, supplier participation is robust. Ninety-two percent of suppliers offered contracts at the competitive bidding prices accepted them, and 63 percent of contract suppliers participating in Round 2 are small businesses. As the DMEPOS competitive bidding program expands, it will contribute to significantly lower costs for taxpayers and beneficiaries.

Prior Authorization for PMD Demonstration

CMS is also moving aggressively to address concerns about fraud related to power mobility devices (PMDs). PMDs are a group of DMEPOS such as power wheelchairs and power operated vehicles (scooters). On September 1, 2012, CMS implemented a prior authorization demonstration for all PMD orders written on or after that date in seven states with high incidences of fraud and error prone providers.[7] The demonstration requires prior authorization, or pre-approval, for PMDs for Medicare beneficiaries who reside in these states (California, Illinois, Michigan, New York, North Carolina, Florida and Texas), helping ensure that a beneficiary's medical condition warrants their medical equipment under existing coverage guidelines.

This approach to protect the Medicare Trust Funds is drawn from the private sector. Prior authorization is currently being used by private insurance for many services and items including PMDs, as well as in other health care programs such as TRICARE and in certain State Medicaid programs. However, unlike some other prior authorization programs, CMS' PMD demonstration

[7] These seven states accounted for 43% of the roughly $606 million spent annually on PMDs. See *Prior Authorization of Power Mobility Devices (PMD) Demonstration Executive Summary*, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Downloads/PMD_PowerpointExecutiveSummary_v3.pdf

program does not automatically deny payment for a PMD if it did not go through prior authorization.[8]

With prior authorization, suppliers and beneficiaries will know before an item is delivered to a beneficiary whether Medicare will pay for the PMD. This helps ensure that Medicare pays only for PMDs that meet the longstanding coverage requirements, thereby limiting fraud, waste and abuse. Further, suppliers and beneficiaries will know before the item is delivered if they will have to pay for the item. Currently, in many cases, if an item is not covered, Medicare beneficiaries have to pay for the entire cost of the item because the PMD is delivered to the beneficiary and then Medicare denies the payment because the coverage criteria has not been met.

Prior authorization is another important tool that will help CMS to reduce fraud and improper payments for PMDs, while continuing to ensure that beneficiaries have access to needed durable medical equipment.

Provider, Supplier, and Claims Screening

While programs like DMEPOS competitive bidding and the PMD prior authorization demonstration are working to bring the rates Medicare pays for DMEPOS in line with market rates and ensure PMD billing is medically necessary, CMS is also using program integrity tools to screen providers, suppliers, and DMEPOS claims.

New Tools in the Affordable Care Act

The Affordable Care Act required CMS to implement risk-based screening of providers and suppliers who want to participate in the Medicare and Medicaid programs and the Children's Health Insurance Program (CHIP), and CMS put these additional requirements in place for newly enrolling and revalidating Medicare providers and suppliers in March 2011. This enhanced screening requires certain categories of providers and suppliers that have historically

[8] If a supplier submits a PMD claim without first seeking prior authorization, the claim will undergo prepayment review. As part of the review process, the DME MAC sends letters to the supplier requesting all documents to support the claim. Once the supplier has submitted all the necessary documentation, the DME MAC conducts a review of the documentation within 60 days. This is the standard time frame for prepayment review. If the DME MAC determines payment is appropriate, the payment is processed.

posed a higher risk of fraud to undergo greater scrutiny prior to their enrollment or revalidation of billing privileges in Medicare, Medicaid, and/or CHIP. Using our new authority, CMS has designated newly enrolling DMEPOS suppliers to the high level of screening prior to enrollment, meaning all new DMEPOS suppliers will receive an announced or unannounced site visit, and will be subject to a fingerprint-based criminal history record checks prior to enrollment once CMS procures an FBI-approved contractor.[9] Current DMEPOS suppliers are designated to the moderate level of screening, and receive an announced or unannounced site visit before the revalidation of their billing privileges. Categories of providers and suppliers in all screening levels are subject to database checks that verify licensure and that a provider or supplier meets all applicable Federal regulations and State requirements.

The Affordable Care Act also required CMS to screen all of the existing 1.5 million Medicare suppliers and providers under these new screening requirements. CMS embarked on an ambitious project to revalidate the enrollment information of all existing providers and suppliers, and these efforts will ensure that only qualified and legitimate providers and suppliers can provide health care items and services to Medicare beneficiaries. Since March 2011, CMS approved for enrollment nearly 458,435 Medicare providers and suppliers, including 30,105 DMEPOS suppliers, under these enhanced screening requirements of the Affordable Care Act. Because of revalidation and other proactive initiatives, CMS has deactivated 159,449 enrollments, including 24,880 DMEPOS enrollments, and revoked 14,009 enrollments, including 1,753 DMEPOS enrollments.[10]

Additionally, the number of DMEPOS suppliers enrolled in Medicare has declined approximately 14 percent over the past six years with no loss of access to DMEPOS for Medicare beneficiaries. The most significant factor in this reduction is the requirement that DMEPOS suppliers become accredited and possess a surety bond of at least $50,000—that is, a bond issued by an entity (the surety) guaranteeing that a DMEPOS supplier will fulfill their financial obligations to Medicare. The surety bond requirement, included in the Balanced

[9] CMS expects to release a contract request to provide the fingerprinting and background checks in spring 2013 with an anticipated award date in late 2013.
[10] "Deactivate" means that the provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information. Revoke means that the provider or supplier's billing privileges are terminated and cannot be reinstated.

Budget Act of 1997 (P.L. 105-33) and in a Final Rule promulgated by CMS on January 2, 2009, required new DMEPOS suppliers to obtain a surety bond by May 4, 2009 and enrolled suppliers by October 2, 2009. Based upon these new requirements, 10,533 DMEPOS suppliers were revoked between October 2009 and December 2009.[11] In addition to those revoked, approximately 1,500 more suppliers voluntarily terminated their enrollment between September 2009 and December 2009, likely to avoid facing revocation actions until they could procure a surety bond or obtain accreditation. Evidence indicates that despite these reductions in DMEPOS supplier enrollment, beneficiaries continue to have access to the DMEPOS they need.

The National Supplier Clearinghouse

CMS uses a variety of contractors to administer and oversee the Medicare fee-for-service program. Each of these contractors has different roles and responsibilities. Some contractors assist CMS in screening providers and suppliers; others combat fraud and identify improper payments. CMS has one dedicated contractor, the National Supplier Clearinghouse (NSC), to receive, review, and process applications from organizations and individuals seeking to become DMEPOS suppliers in the Medicare program. NSC's process involves implementing safeguards to ensure only legitimate suppliers enter and remain in the Medicare program, and includes announced and unannounced site visits to prospective suppliers to determine that they meet required supplier standards; checking that the supplier has all applicable licenses; checking that the supplier and its principals are not excluded from participating in Federal programs by virtue of being on General Service Administration (GSA) or OIG excluded lists; and checking that the supplier meets accreditation and surety bond requirements.

Stopping fraud and abuse also includes monitoring DMEPOS suppliers. The NSC assigns fraud level indicators to assist in its expanded reviews of suppliers, which include increased unannounced on-site reviews, license expiration checks, and phone calls to suppliers. The NSC also coordinates and assists in fraud-fighting efforts with CMS, law enforcement, and other contractors on an ongoing basis.

[11] Due to the large number of last minute filings, 2,803 of those revocations were subsequently overturned as suppliers were able to demonstrate compliance with both requirements.

Durable Medical Equipment Medicare Administrative Contractors

In addition to having a contractor dedicated to screening only DMEPOS suppliers in the Medicare program, CMS also contracts with entities dedicated to screening and analyzing DMEPOS claims. The Durable Medical Equipment Medicare Administrative Contractors (DME-MACs) process claims and handle the first level of providers' claims appeals. They implement all Medicare payment system changes, and conduct training and outreach regularly to suppliers to educate them on proper claims coding and new Medicare payment policies. While DME-MACs focus on claims processing, they also play important roles in CMS' anti-fraud efforts. For instance, DME-MACs put automated edits in place to identify and address claim coding errors, mutually exclusive claims, or medically unlikely claims. They regularly analyze claims data received to identify suppliers with patterns of errors or unusually high volumes of particular claims types, and to develop additional prepayment edits. They also coordinate the timing and implementation of these edits with other contractors. When DME-MACs identify potential fraud, they send leads to antifraud contractors to investigate further.

A New Approach to Program Integrity

Beyond CMS' programs to pay DMEPOS suppliers market rates and screen providers and suppliers, CMS is using other new approaches to prevent DMEPOS fraud. CMS' approach involves pre-payment claims screening, targeted use of contractors for essential program integrity functions, and partnership with law enforcement to investigate fraud.

Zone Program Integrity Contractors (ZPICs)

Zone Program Integrity Contractors (ZPICs) help CMS perform a variety of program integrity functions at a regional level.[12] They are dedicated exclusively to the prevention, detection, and recovery of potential fraud, waste, or abuse, and coordinate with their contractor partners to implement administrative actions, including claim edits, payment suspensions, and revocations. ZPICs also refer overpayments for collection.

[12] Six of the seven ZPICs have been awarded.

The ZPICs' main responsibilities are to:

- Investigate leads generated by the new Fraud Prevention System (FPS) and a variety of other sources;
- Perform data analysis to identify cases of suspected fraud, waste, and abuse;
- Make recommendations to CMS for appropriate administrative actions to protect Medicare Trust Fund dollars;
- Make referrals to law enforcement for potential prosecution;
- Provide support for ongoing investigations;
- Provide feedback and support to CMS to improve the FPS; and
- Identify improper payments to be recovered.

The Fraud Prevention System

On June 30, 2011, CMS launched the Fraud Prevention System (FPS). Created under the Small Business Jobs Act of 2010, the FPS analyzes all Medicare fee-for-service claims, including DMEPOS claims, using risk-based algorithms developed by CMS and the private sector, prior to payment, allowing CMS to take prompt action where appropriate. CMS uses the FPS to target investigative resources to suspect claims and providers and swiftly impose administrative action when warranted. For example, ZPIC investigators formerly had to check multiple systems to determine whether a beneficiary ever visited the doctor who billed Medicare for services and supplies. The FPS has consolidated the dispersed pieces of potentially-related claims data – beneficiary visits with a doctor or orders for DMEPOS billed under Part B, and hospital and other provider services billed under Part A – enabling CMS and the ZPICs to automatically see the full picture.

Importantly, the FPS is a resource management tool; the system automatically sets priorities for the ZPICs workload to target investigative resources to suspect claims and providers, and swiftly impose administrative action when warranted. The system generates alerts in priority order, allowing program integrity analysts to quickly investigate the most egregious, suspect, or aberrant activity. CMS and the ZPICs use the FPS information to identify, stop, and prevent improper payments utilizing a variety of administrative tools and actions, including pre-payment

review, claim denials, payment suspensions, revocation of Medicare billing privileges, and referrals to law enforcement.

Early results from the FPS show significant promise and CMS expects results to increase as the system matures over time. As reported in our Report to Congress,[13] in its first year of implementation, the FPS:

- Prevented or identified an estimated $115.4 million in improper payments;
- Achieved a positive return on investment, saving an estimated $3 for every $1 spent in the first year;
- Generated leads for 536 new fraud investigations;
- Provided new information for 511 existing investigations; and
- Triggered 617 provider interviews and 1,642 beneficiary interviews regarding suspect claims or provider activity.

The ZPICs' workload also incorporates lessons learned from the DME Stop Gap project, which was developed in response to the escalation in DMEPOS fraud and the delay in implementation of DMEPOS competitive bidding mandated by MIPPA. This two-year project was initiated in FY 2009 to enhance detection and prevention activities in connection with fraud, waste and abuse in DMEPOS in seven States (California, Florida, Illinois, Michigan, North Carolina, New York and Texas). The project was intended to address fraud involving high risk suppliers, ordering physicians, DMEPOS items, and beneficiaries in each area. Under this project, CMS and its contractors first identified and then interviewed or conducted site visits to the highest paid and highest risk DMEPOS suppliers, ordering physicians, and utilizing beneficiaries, allowing CMS to identify and scrutinize the highest billed and highest risk DMEPOS equipment and supplies. Based on the findings, appropriate administrative actions were initiated. The second year of the project concluded on September 30, 2011 and the results to date include onsite interviews and reviews of 5,371 high risk providers, suppliers, and beneficiaries; implementation of 15,470 claims processing edits to prevent improper payment (with associated $36.4 million in denied claims); $69 million in requested overpayments; 1,240 new investigations opened; and

[13] Report to Congress: Fraud Prevention System First Implementation Year 2012
http://www.stopmedicarefraud.gov/fraud-rtc12142012.pdf

479 suppliers revoked or deactivated. As a result of the success of this project, all lessons learned have been incorporated into the ZPIC core functions related to combating fraud, waste and abuse in DMEPOS suppliers.

Recovery Audit Contractors (RACs)

The Recovery Audit Contractors are tasked with identifying a wide range of improper payments – including, but not limited to fraud – and making recommendations to CMS about how to reduce improper payments in the Medicare program. In the fee-for-service Medicare program, RACs have identified several vulnerabilities where CMS has implemented corrective actions to prevent future improper payments. For example, CMS' contractors have implemented edits to stop the payment of claims provided after a beneficiary's date of death, stop the payment of durable medical equipment claims while the beneficiary is receiving care in an inpatient setting, and stop the payment for individual services that should have been bundled into another payment. In the past, RAC reviews in Medicare have focused on incorrect coding, erroneous billing practices, and billing for the wrong setting of care. Unlike other Medicare program integrity contractors, RACs' reviews are more likely to identify overpayments from providers who are still enrolled and billing in Medicare. If RACs identify or uncover potential fraud, they are required to report it directly to CMS, and to refrain from reviewing claims that are subject to an ongoing fraud investigation. In FY 2012, Medicare fee-for-service RACs collected nearly $2.3 billion in overpayments.

Partnership with Law Enforcement

CMS is also collaborating in an unprecedented way with the private sector, law enforcement, and our State partners to develop best practices in our fight against health care fraud. At the Command Center, for example, advanced technologies and a collaborative environment allow multi-disciplinary teams of experts and decision makers to more efficiently coordinate policies and case actions, reduce duplication of efforts, and streamline fraud investigations for more immediate administrative action. Since its official establishment on July 31, 2012, CMS has led 61 missions that included over 450 unique participants from CMS and our partners, including the OIG and the Federal Bureau of Investigations (FBI) in the new Command Center. These collaborative activities enable CMS to take administrative actions, such as revocations of

Medicare billing privileges and payment suspensions, more quickly and efficiently. CMS is also working with other Federal agencies in the Command Center to pool resources to tackle cross-cutting issues surrounding fraud prevention.

In addition, joint investigations by the Department of Justice (DOJ), CMS, and OIG have yielded significant recoveries for the Medicare fee-for-service program. Since its creation in May 2009, Health Care Fraud Prevention & Enforcement Action Team (HEAT), has played a critical role in identifying new enforcement initiatives and expanding data sharing to a cross-government health care fraud data intelligence sharing workgroup. In recent years, numerous DMEPOS suppliers have been charged and convicted of defrauding the Medicare program and many have had their Medicare billing privileges revoked as a result of OIG investigations. Examples include the 20 DMEPOS company owners and marketers, most of them in the Los Angeles area, who were charged in 2009 with allegedly billing Medicare for more than $26 million in fraudulent claims for power wheelchairs, orthotics, and hospital beds.[14] More recently, a Louisiana man was sentenced to 180 months in prison for participating in a health care fraud scheme that defrauded Medicare of more than $21 million by billing for power wheelchairs, leg and arm braces, and other durable medical equipment that was never provided to beneficiaries and/or were not medically unnecessary.[15]

CMS' collaborative approach to fraud-fighting is paying off. In fiscal year (FY) 2012, fraud detection and enforcement efforts in the Health Care Fraud and Abuse Control (HCFAC) program resulted in the record-breaking recovery of $4.2 billion in taxpayer dollars from individuals trying to defraud Federal health care programs serving seniors and taxpayers. Over the last three years, the average return on investment of the HCFAC program is $7.90 for every dollar spent. Since 1997, HCFAC activities have returned more than $23 billion to the Medicare Trust Funds.

[14] http://oig.hhs.gov/oei/reports/oei-04-09-00260.asp
[15] http://www.justice.gov/opa/pr/2012/August/12-crm-1032.html

Conclusion

Effective administration of the Medicare DMEPOS benefit is an essential part of CMS' mission to ensure the health care security of millions of Medicare beneficiaries. While the DMEPOS benefit has long been a source of waste and fraud, aggressive approaches that that bring Medicare payments for DMEPOS in line with market rates, that safeguard against erroneous DMEPOS billing, and that prevent inappropriate suppliers from enrolling are making DMEPOS less attractive to fraudsters and lowering Medicare's DMEPOS expenditures. The 42 percent reduction in DMEPOS expenditures over the competitive bidding program's first year is a testament to the success that can be achieved when CMS and Congress partner together to safeguard the Medicare Trust Funds. CMS is committed to addressing concerns about improper payments and fraud related to the Medicare DMEPOS benefit, and ensuring that our contractors quickly identify and correct improper payments and potential fraud. That is why, in addition to competitive bidding, CMS is transforming its approach to program integrity, focusing on preventing fraud before it happens. I look forward to working with this Subcommittee and the Congress to continue CMS' progress in modernizing the way Medicare pays for and monitors the DMEPOS benefit.

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AdvanceMed's Response to Durable Medical Equipment (DME) Fraud in ZPIC Zones 2 and 5

Written Testimony Provided to:

Committee on Homeland Security and Governmental Affairs
Subcommittee on Financial and Contracting Oversight

April 22, 2013

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The Centers for Medicare and Medicaid Services (CMS) initiated the Zone Program Integrity Contractors (ZPIC) program in 2008. Seven zones were created based on the newly established Medicare Administrative Contractor (MAC) jurisdictions. As a result of the seven zones, new entities entitled Zone Program Integrity Contractors (ZPICs) were created to perform program integrity for Medicare Parts A, B, Durable Medical Equipment (DME), Home Health and Hospice (HH+H) and the Medicare-Medicaid (Medi–Medi) Data Match Program. The ZPIC Umbrella Statements of Work (SOW) encompass all of the fundamental activities that may be required of a ZPIC. However, work is not performed under the umbrella SOW since individual Task Orders are awarded under the Indefinite Delivery Indefinite Quantity (IDIQ) contract for specific requirements. Medicare Parts C & D were also included in the ZPIC Umbrella contract, but have not yet been exercised as Task Orders under the current contracts.

CMS awarded the Umbrella IDIQ contract for ZPIC Zone 5 to AdvanceMed in February of 2009. As the ZPIC for Zone 5, AdvanceMed currently conducts fraud, waste, and abuse detection and investigation in 10 states (Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia). AdvanceMed has established four operational Medi-Medi data matching programs with Arkansas, Georgia, Mississippi, and North Carolina. The Medi-Medi project for Alabama is currently in the implementation phase with an anticipated operational date in July 2013.

The value of the Zone 5 contract (including Task Orders 1 and 2), including all funding actions to date and the value of unexercised options is $113,564,992.

CMS awarded the Umbrella IDIQ contract, along with Task Orders 1 and 2, for ZPIC Zone 2 to AdvanceMed in September 2009. AdvanceMed currently conducts fraud, waste, and abuse detection and investigation in the 14 states located in Zone 2 (Alaska, Arizona, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming). Zone 2 also has three fully operational Medi-Medi programs in Utah, Missouri and Iowa and is currently implementing two more programs in Nebraska and Arizona.

The value of the Zone 2 contract (including Task Orders 1 and 2), including all funding actions to date and the value of unexercised options is $81,893,564.

The ZPIC contract vehicle includes provisions for an Award Fee. The current award fee for Task Order One (Fee-For-Service Task) is based on a performance evaluation of the contractor's overall Quality of Service and a self-evaluation of performance related to improvement of administrative actions by the contractor and demonstration of a mechanism to track overpayment recoupments completed by the MACs. The Task Order Two (Medi-Medi) Award Fee Criteria is based on a performance evaluation of either Quality of Deliverables (if the state is still in implementation) or Quality of Service (if fully operational) and Business Relations.

The Award Fee Plans detail the criteria and evaluation process for determining any Award Fee to be paid to the contractor.

Fundamental activities of ZPICs are those that help ensure payments are appropriate and consistent with Medicare and/or Medicaid coverage, coding, and audit policy. Furthermore, these activities are aimed at identifying, preventing, or correcting potential fraud, waste and abuse and include, but are not limited to, the following:

- performing benefit integrity investigations;
- implementing appropriate administrative actions such as prepayment review, auto deny edits etc.;
- coordinating potential fraud, waste and abuse activities with the appropriate Medicare contractors and other stakeholders;
- referring cases to law enforcement;
- conducting post payment medical review activities;

- proactive data analysis
- screening of reactive leads (i.e., complaints);
- matching and analysis of Medicare and Medicaid data; and
- responding to law enforcement requests and providing subject matter expertise to law enforcement

The following are examples of common fraud schemes which have been identified within the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Medicare benefit:

- **Telemarketing fraud scheme**

  In this fraud scheme, a supplier uses telephone or other electronic communications to contact individual Medicare beneficiaries in order to solicit them for equipment, prosthetics, orthotics, or supplies. Typically suppliers identify a general medical complaint such as back or neck pain, and then a neck or back brace is shipped to the beneficiary. Subsequently, the item is billed to and paid by Medicare.

  Telemarketing scams by suppliers have become more sophisticated with the sharing of beneficiary identifying information between suppliers and clearinghouses used to make mass calls. Companies many times will offer free items such as cookbooks, glucometers, and other items in an attempt to get beneficiaries to provide their identifying information.

  DME suppliers are prohibited from soliciting beneficiaries absent meeting one of the following criteria:

  1. The beneficiary has given written permission to the supplier to make contact by telephone;
  2. The contact is regarding a covered item that the supplier has already furnished the beneficiary; or
  3. The supplier has furnished at least one covered item to the beneficiary during the preceding 15 months.

  As part of CMS' efforts to identify and resolve complaints more efficiently, effectively and timely, AdvanceMed has been contracted to conduct a Pilot Project that involves receiving, reviewing, and resolving complaints that are received by 1-800 Medicare. The Beneficiary Complaint Pilot Project (BCPP) was initiated in Zone 5 during 2011. The project involves the receipt of all Medicare complaints (Medicare Parts A, B, DME, Home Health and Hospice) alleging fraud that are within the Zone 5 jurisdiction. This process does not rely on the MAC to screen and forward those complaints to the ZPIC that they believe involve potential fraud, as is the process in all other Zones. The ZPIC (Zone 5) receives all complaints and screens them within 5 days and then notifies the MACs of those that are not issues involving potential fraud, so that they may complete the process of resolving the complaints that the ZPIC will not pursue. As a result of this project, the ZPIC (Zone 5) has been able to take actions to stop fraudulent activity much more quickly than under the old process, that sometimes resulted in delays of 4-6 weeks to receive the complaint (by which time the fraudulent provider may have moved on to other beneficiaries or locations) and many complaints were not forwarded at all.

  The BCPP receives allegations of telemarketing from beneficiaries alleging they have been contacted by DME companies, or their subcontractors, promising medical equipment. When AdvanceMed receives these complaints, beneficiaries are interviewed by staff and subsequently asked to sign an attestation affirming that the contact was made without their consent and that the beneficiary does not want or need the offered DME. AdvanceMed then places an auto deny edit in the claims processing system to prevent the suspect supplier from billing the unnecessary equipment for the beneficiary. The beneficiary's health insurance claim number (HIC) is also added to the national compromised HIC number database for further tracking and future analysis. Additionally, the supplier is sent an educational warning letter about the telemarketing practice and the matter is referred to the National Supplier Clearinghouse (NSC) for review and consideration of revocation should the practices continue.

In October 2011, Zone 2 conducted proactive data analysis to review beneficiaries receiving excessive amounts of glucose strips. Based on the proactive study, an investigation was opened. Subsequent analysis and beneficiary interviews showed that multiple DME suppliers were selling glucose test strips and other diabetic supplies to the same beneficiaries at the same time. It was discovered that some DME suppliers were making unwanted and unsolicited marketing phone calls to beneficiaries for glucose test strips and other DME supplies. Often, the telemarketers were successful in obtaining Medicare beneficiary information, resulting in orders and bills for unwanted and unnecessary supplies.

Further data analysis of claims data and information from CMS DME complaint logs was made regarding telemarketing complaints made to CMS. The analysis showed a number of DME suppliers who shared beneficiaries and who could be linked through the complaint logs to telemarketing companies. Zone 2 staff compiled a "target" list consisting of beneficiaries purportedly receiving supplies from more than one DME supplier. Staff also compiled a "source" list of beneficiaries for each DME supplier. By cross-referencing the two lists, analysts found between 12% and 63% of shared beneficiaries for each DME supplier.

Since October 2011, Zone 2 has opened at least six investigations involving prohibited telemarketing by DME suppliers. Four of these investigations have been referred to and accepted by the HHS OIG and are actively being investigated. In addition, several immediate advisements were sent and accepted by the OIG.

- **Services not provided fraud scheme**

  In this fraud scheme, a supplier bills Medicare for equipment, prosthetics, orthotics, or supplies which were never delivered or provided to the Medicare beneficiary.

- **Items not medically necessary fraud scheme**

  In this fraud scheme, a supplier bills Medicare for equipment, prosthetics, orthotics, or supplies which the beneficiary did not require, or for which there was no medical need.

- **No relationship with the ordering physician fraud scheme**

  In this fraud scheme, a supplier has an arrangement with a physician where the DME supplier submits orders for equipment, prosthetics, orthotics, or supplies for approval, although the physician has no prior relationship with the patient, having never assessed them for the need for the supplies. Typically these physicians are paid a fee for their services based on the volume of orders they sign.

- **False front suppliers**

  In this fraud scheme, a supplier number is established for a DME supplier which does not exist. There is no physical location for this supplier, nor do they possess the appropriate equipment or supplies to be able to deliver to the Medicare beneficiaries. This "supplier" subsequently obtains Medicare beneficiary numbers, through identity theft or by purchasing them directly from beneficiaries, and bills for supplies which are never delivered or provided to the Medicare beneficiary.

  Zone 2 performs national False Front Provider detections for CMS. False Front Providers are the products of individuals who work alone or in concert with others to steal the identity of valid Medicare providers and then submit false claims directing Medicare payments to new locations. In 2011 and 2012, Zone 2 detected 195 such instances of which 13 were investigated by Zone 2 and 182 were referred by Zone 2 to other ZPICs for investigation. The majority of these false front suppliers portray themselves as ambulance companies, laboratories, and/or physician practices.

  The goal of this effort is to detect these situations before any payments can be made. Of the 195 detected in 2011 and 2012, 87 were identified before payments were made. We estimate that the early detection of the 87 saved $24,900,000 based on amounts that fully operating False Front Provider

schemes have achieved. Over the entire history of the project, Zone 2 has detected 488 false Front Providers.

- **Provision of DME while a patient is under hospice care or residing in a skilled nursing facility fraud scheme**

  When a Medicare beneficiary is under the care of a hospice or a skilled nursing facility, the equipment or supplies necessary for the treatment of the diagnosis related that admission is often covered under the hospice benefit or within the payment to the skilled nursing facility. In this fraud scheme, the supplier (who may be affiliated with the hospice or with the skilled nursing facility) "unbundles" the equipment or supplies and bills them to Medicare separately, rather than including it within the reimbursement for the hospice or skilled nursing care.

ZPICs have a number of administrative tools available for use when dealing with the types of allegations described above. The ZPICs can take the following action(s) against suppliers:

- **Prepay medical review:** This action allows the ZPIC to stop all claim payments for suppliers until the medical records for each claim can be ordered, received, and reviewed to determine if the DME supplies should be paid for.

- **Postpay medical review:** This administrative action involves the medical review of claim payments that have been made to a supplier. ZPICs identify claims to be reviewed through data analysis and may determine that statistical sampling is necessary. The use of statistical sampling allows the ZPIC to extrapolate overpayments to a universe of claims related to the fraud issue being reviewed. Statistical sampling and overpayment extrapolation is overseen by statisticians following protocols approved by CMS and the Office of Inspector General (OIG).

- **Payment suspension:** This action, with approval from CMS, allows the ZPIC to stop payments from being made directly to a DME supplier for claims that have been processed. The claim payments are placed in an escrow account pending review by the ZPIC. Payment suspensions are used when a credible allegation of fraud is being reviewed or a potential overpayment exists but has not yet been calculated.

- **Initiation of auto deny edits:** Auto deny edits are placed in the claims payment system in order to deny payments for supplies and services that have been determined to be unnecessary or inappropriate based on previous medical reviews, investigational determinations, MAC local coverage determinations, and/or CMS policy. These edits can be initiated based on a specific beneficiary HIC, supplier number, or a co de or set of codes that identify specific pieces of DME. These edits create automatic claims denials before payments are made, and they do not require medical review prior the denial being effectuated in the system.

- **Revocation:** Revocations involve the termination of a supplier or provider's ability to bill Medicare for services rendered. Revocation actions are reviewed by CMS for approval. Referrals for revocation of a DME supplier typically involve behavior such as failing to meet conditions of participation, failure to adhere to education, and/or continued telemarketing following warnings and education.

- **Referral to law enforcement:** In addition to the administrative actions listed above, ZPICs can also refer suspected allegations of fraud to state and federal law enforcement for further investigation and prosecution.

The table below shows requested outcomes of AdvanceMed's DME related actions and activities taken between January 1, 2011 and December 31, 2012 as reported monthly during the time period. The information includes data from Task Orders 1 and 2, as well as results from Zone 5's DME Stop Gap Project in North Carolina.

Activity	Zone 2	Zone 5
Value of overpayments referred to MAC for collection	$810,768.53[1]	$115,477,435.26[2]
Number of overpayment actions referred for collection	6[3]	128[4]
Overpayment amounts recovered by MAC	$46,016.47[5]	$ 13,971,864.39
Number of cases referred to law enforcement	13	32
Total estimated dollars associated with cases referred	$41,663,941.02	$ 21,203,541.19
Dollar value of prepay claims denied	$3,106,705.15	$ 19,021,822.92
Number of payment suspension requests	0	7
Number of recommended auto-deny edits	50	1,730
Dollar value of recommended auto-deny edits	$13,094.00	$ 21,709,959.00
Number of revocations recommended	0	23

[1] This figure represents the total reported in CMS monthly reports during the time period. The initial response provided on April 16, 2013 was understated by $3,920.76.
[2] This figure includes the totals from the North Carolina DME Stop Gap Project. The DME Stop Gap information was not included in the April 16, 2013 response.
[3] This total represents the number reported in CMS monthly reports during the time period. The initial response provided on April 16, 2013 was understated by one (1) referral. See footnote number 1 for related amount.
[4] This figure represents the total number of overpayment referrals reported in CMS monthly reports. CMS does not capture the number of overpayment referrals for Task Order 2. The total number of overpayment referrals, including Task Order 2 is 135.
[5] This figure represents the total reported in CMS monthly reports during the time period. The initial response provided on April 16, 2013 was overstated by $583.30. This difference was caused by a calculation error.

Total DME Payments between 2009-2012:
$34.4 Billion
Estimated Proper Payments 37% $ 12.4 billion
Estimated Improper Payments 63% $22 billion

Table A: Estimated Improper Payments for Durable Medical Equipment (DME)

	2009	2010	2011	2012
Total DME Payments	$8.8 billion	$8.3 billion	$8.5 billion	$8.8 billion
Error Rate	52%	74%	61%	66%
Est. Improper Payments	$4.6 billion	$6.1 billion	$5.2 billion	$5.8 billion

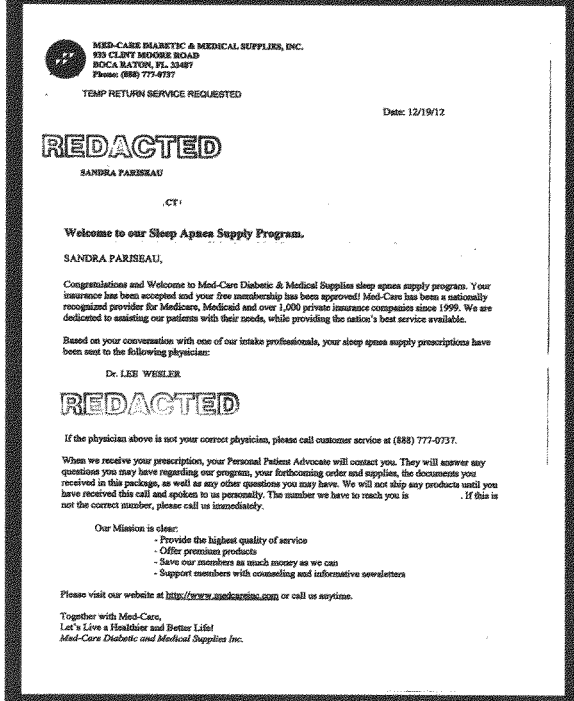
Table B: Amounts Recovered from Overpayments				
	2009	**2010**	**2011**	**2012**
Est. Improper Payments	$4.6 billion	$6.1 billion	$5.2 billion	$5.8 billion
Amount Recovered	--	$18.8 million	$34 million	*Not yet available*

Improper Payments Unrecovered By CMS
Unrecovered payments: $15,847,200,000
Recovered payments: $52,800,000

Table C: Medicare Payments to Med-Care					
	2009	**2010**	**2011**	**2012**	**Total (2009-2012)**
Total Medicare Payments	$9.3 million	$15.4 million	$25 million	$34.8 million	$84.5 million
Medicare Claims Paid	74,393	123,312	201,506	261,626	660,837

Table D: Medicare Payments to U.S. Healthcare					
	2009	**2010**	**2011**	**2012**	**Total (2009-2012)**
Total Medicare Payments	$0	$3.1 million	$11.8 million	$39.8 million	$54.7 million
Medicare Claims Paid	0	20,067	79,962	197,666	297,695

Letters from Med-Care Diabetic & Medical Supplies, Inc. to Sandra Pariseau



MED-CARE DIABETIC & MEDICAL SUPPLIES, INC.
933 CLINT MOORE ROAD
BOCA RATON, FL. 33487
Phone: (888) 777-0737

TEMP RETURN SERVICE REQUESTED

Date: 12/19/12

REDACTED

SANDRA PARISEAU

, CT

Welcome to our Sleep Apnea Supply Program.

SANDRA PARISEAU,

Congratulations and Welcome to Med-Care Diabetic & Medical Supplies sleep apnea supply program. Your insurance has been accepted and your free membership has been approved! Med-Care has been a nationally recognized provider for Medicare, Medicaid and over 1,000 private insurance companies since 1999. We are dedicated to assisting our patients with their needs, while providing the nation's best service available.

Based on your conversation with one of our intake professionals, your sleep apnea supply prescriptions have been sent to the following physician:

Dr. LEE WESLER

REDACTED

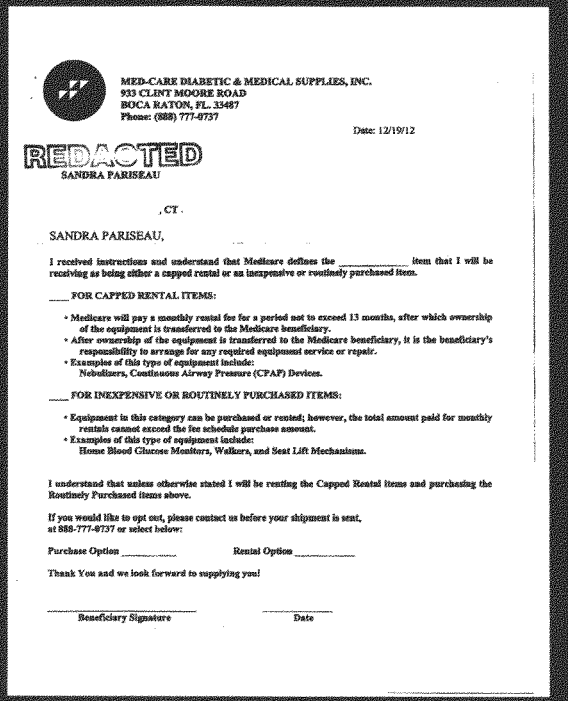
If the physician above is not your correct physician, please call customer service at (888) 777-0737.

When we receive your prescription, your Personal Patient Advocate will contact you. They will answer any questions you may have regarding our program, your forthcoming order and supplies, the documents you received in this package, as well as any other questions you may have. We will not ship any products until you have received this call and spoken to us personally. The number we have to reach you is . If this is not the correct number, please call us immediately.

Our Mission is clear:
- Provide the highest quality of service
- Offer premium products
- Save our members as much money as we can
- Support members with counseling and informative newsletters

Please visit our website at http://www.medcareinc.com or call us anytime.

Together with Med-Care,
Let's Live a Healthier and Better Life!
Med-Care Diabetic and Medical Supplies Inc.



MED-CARE DIABETIC & MEDICAL SUPPLIES, INC.
933 CLINT MOORE ROAD
BOCA RATON, FL. 33487
Phone: (888) 777-0737

Date: 12/19/12

REDACTED

SANDRA PARISEAU

, CT

SANDRA PARISEAU,

I received instructions and understand that Medicare defines the _____ item that I will be receiving as being either a capped rental or an inexpensive or routinely purchased item.

____ FOR CAPPED RENTAL ITEMS:

- Medicare will pay a monthly rental fee for a period not to exceed 13 months, after which ownership of the equipment is transferred to the Medicare beneficiary.
- After ownership of the equipment is transferred to the Medicare beneficiary, it is the beneficiary's responsibility to arrange for any required equipment service or repair.
- Examples of this type of equipment include:
  Nebulizers, Continuous Airway Pressure (CPAP) Devices.

____ FOR INEXPENSIVE OR ROUTINELY PURCHASED ITEMS:

- Equipment in this category can be purchased or rented; however, the total amount paid for monthly rentals cannot exceed the fee schedule purchase amount.
- Examples of this type of equipment include:
  Home Blood Glucose Monitors, Walkers, and Seat Lift Mechanisms.

I understand that unless otherwise stated I will be renting the Capped Rental items and purchasing the Routinely Purchased items above.

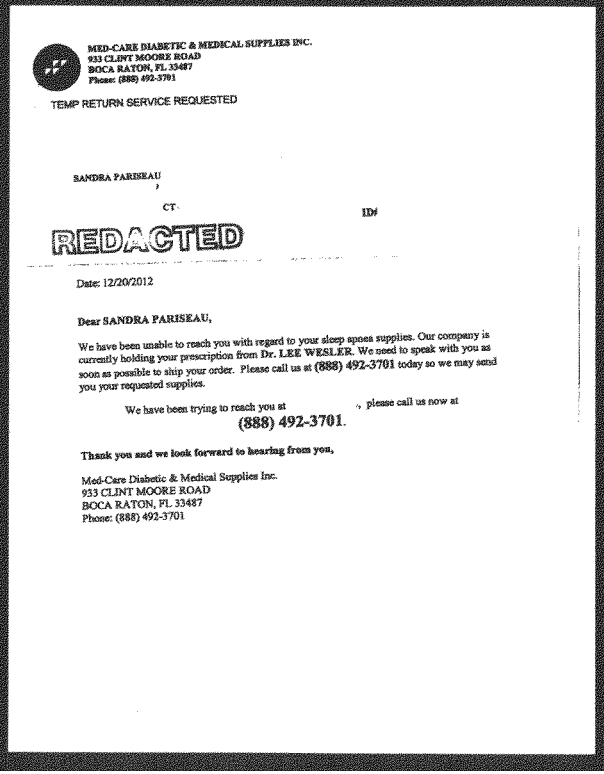
If you would like to opt out, please contact us before your shipment is sent, at 888-777-0737 or select below:

Purchase Option _____ Rental Option _____

Thank You and we look forward to supplying you!

_____ _____
Beneficiary Signature Date

Letters from Med-Care Diabetic & Medical Supplies, Inc. to Sandra Pariseau



MED-CARE DIABETIC & MEDICAL SUPPLIES INC.
933 CLINT MOORE ROAD
BOCA RATON, FL 33487
Phone: (888) 492-3701

TEMP RETURN SERVICE REQUESTED

SANDRA PARISEAU

CT ID#

REDACTED

Date: 12/20/2012

Dear SANDRA PARISEAU,

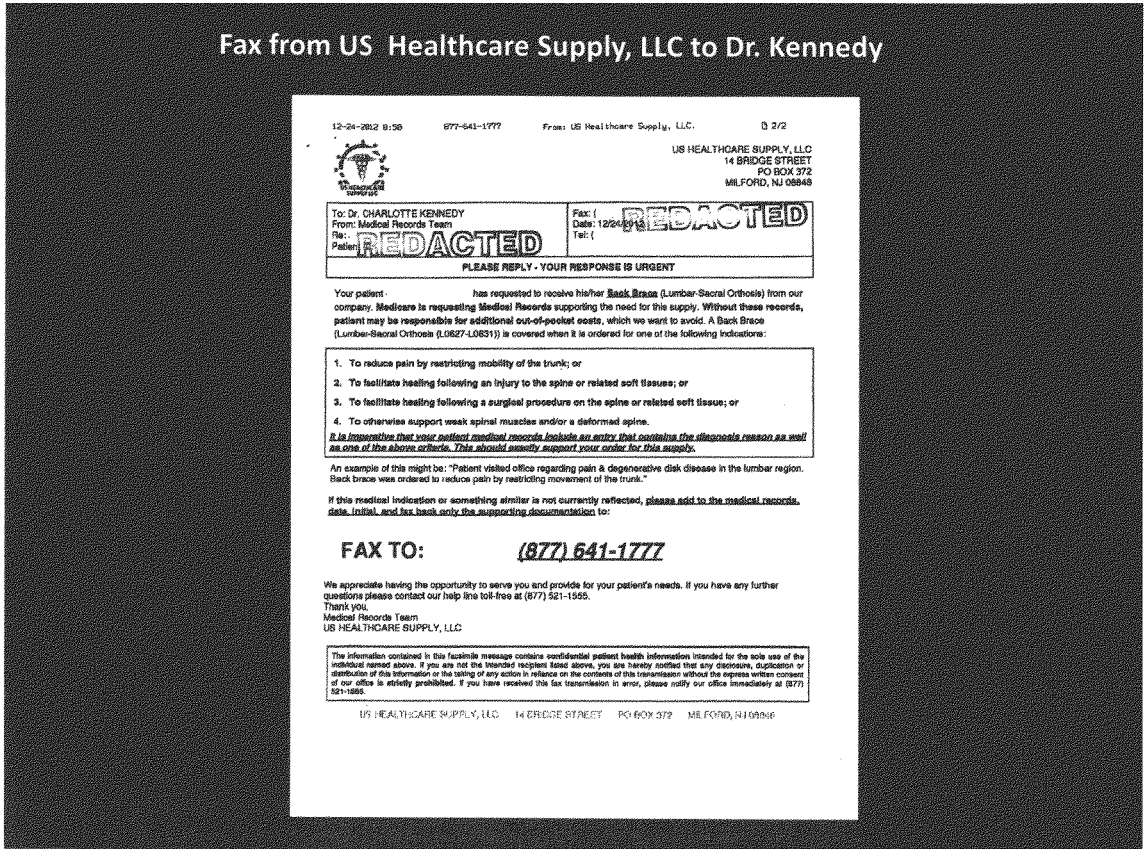
We have been unable to reach you with regard to your sleep apnea supplies. Our company is currently holding your prescription from Dr. LEE WESLER. We need to speak with you as soon as possible to ship your order. Please call us at (888) 492-3701 today so we may send you your requested supplies.

We have been trying to reach you at , please call us now at (888) 492-3701.

Thank you and we look forward to hearing from you,

Med-Care Diabetic & Medical Supplies Inc.
933 CLINT MOORE ROAD
BOCA RATON, FL 33487
Phone: (888) 492-3701

Fax from US Healthcare Supply, LLC to Dr. Kennedy



12-24-2012 8:58 877-641-1777 From: US Healthcare Supply, LLC. 2/2

US HEALTHCARE SUPPLY, LLC
14 BRIDGE STREET
PO BOX 372
MILFORD, NJ 08848

To: Dr. CHARLOTTE KENNEDY
From: Medical Records Team
Re:
Patient: REDACTED

Fax: (
Date: 12/24/2012 REDACTED
Tel: (

PLEASE REPLY - YOUR RESPONSE IS URGENT

Your patient · has requested to receive his/her **Back Brace** (Lumbar-Sacral Orthosis) from our company. **Medicare is requesting Medical Records** supporting the need for this supply. **Without these records, patient may be responsible for additional out-of-pocket costs**, which we want to avoid. A Back Brace (Lumbar-Sacral Orthosis (L0627-L0631)) is covered when it is ordered for one of the following indications:

1. **To reduce pain by restricting mobility of the trunk; or**
2. **To facilitate healing following an injury to the spine or related soft tissues; or**
3. **To facilitate healing following a surgical procedure on the spine or related soft tissue; or**
4. **To otherwise support weak spinal muscles and/or a deformed spine.**

It is imperative that your patient medical records include an entry that contains the diagnosis reason as well as one of the above criteria. This should exactly support your order for this supply.

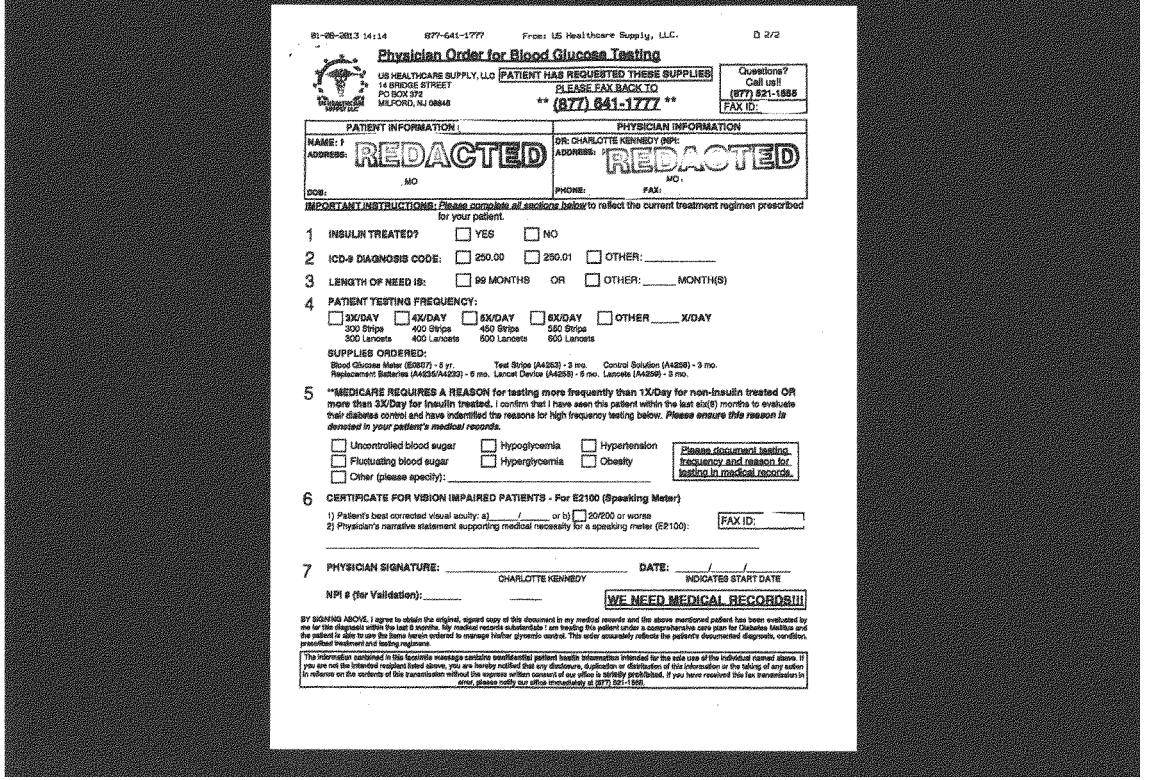
An example of this might be: "Patient visited office regarding pain & degenerative disk disease in the lumbar region. Back brace was ordered to reduce pain by restricting movement of the trunk."

If this medical indication or something similar is not currently reflected, please add to the medical records, date, initial, and fax back only the supporting documentation to:

FAX TO: *(877) 641-1777*

We appreciate having the opportunity to serve you and provide for your patient's needs. If you have any further questions please contact our help line toll-free at (877) 521-1555.
Thank you.
Medical Records Team
US HEALTHCARE SUPPLY, LLC

Fax from US Healthcare Supply, LLC to Dr. Kennedy



01-08-2013 14:14 877-641-1777 From: US Healthcare Supply, LLC P 2/2

Physician Order for Blood Glucose Testing

US HEALTHCARE SUPPLY, LLC
14 BRIDGE STREET
PO BOX 372
MILFORD, NJ 08848

PATIENT HAS REQUESTED THESE SUPPLIES
PLEASE FAX BACK TO
** (877) 641-1777 **

Questions? Call us!! (877) 521-1855
FAX ID:

PATIENT INFORMATION	PHYSICIAN INFORMATION
NAME: / ADDRESS: REDACTED , MO	DR: CHARLOTTE KENNEDY (NPI: REDACTED ADDRESS: REDACTED MO ,
DOB:	PHONE: FAX:

IMPORTANT INSTRUCTIONS: *Please complete all sections below* to reflect the current treatment regimen prescribed for your patient.

1 INSULIN TREATED? ☐ YES ☐ NO

2 ICD-9 DIAGNOSIS CODE: ☐ 250.00 ☐ 250.01 ☐ OTHER: _____

3 LENGTH OF NEED IS: ☐ 99 MONTHS OR ☐ OTHER: _____ MONTH(S)

4 PATIENT TESTING FREQUENCY:

☐ 3X/DAY 300 Strips 300 Lancets ☐ 4X/DAY 400 Strips 400 Lancets ☐ 5X/DAY 450 Strips 500 Lancets ☐ 6X/DAY 550 Strips 600 Lancets ☐ OTHER ____ X/DAY

SUPPLIES ORDERED:

Blood Glucose Meter (E0607) - 5 yr. Test Strips (A4253) - 3 mo. Control Solution (A4256) - 3 mo.
Replacement Batteries (A4235/A4233) - 6 mo. Lancet Device (A4258) - 5 mo. Lancets (A4259) - 3 mo.

5 **MEDICARE REQUIRES A REASON for testing more frequently than 1X/Day for non-insulin treated OR more than 3X/Day for insulin treated. I confirm that I have seen this patient within the last six(6) months to evaluate their diabetes control and have indentified the reasons for high frequency testing below. ***Please ensure this reason is denoted in your patient's medical records.***

☐ Uncontrolled blood sugar ☐ Hypoglycemia ☐ Hypertension
☐ Fluctuating blood sugar ☐ Hyperglycemia ☐ Obesity
☐ Other (please specify): _____

Please document testing frequency and reason for testing in medical records.

6 CERTIFICATE FOR VISION IMPAIRED PATIENTS - For E2100 (Speaking Meter)

1) Patient's best corrected visual acuity: a)_____/_____ or b) ☐ 20/200 or worse
2) Physician's narrative statement supporting medical necessity for a speaking meter (E2100):

FAX ID:

_____

7 PHYSICIAN SIGNATURE: _____ DATE: ____/____/____
CHARLOTTE KENNEDY INDICATES START DATE

NPI # (for Validation):_____ _____

WE NEED MEDICAL RECORDS!!!

BY SIGNING ABOVE, I agree to obtain the original, signed copy of this document in my medical records and the above mentioned patient has been evaluated by me for this diagnosis within the last 6 months. My medical records substantiate I am treating this patient under a comprehensive care plan for Diabetes Mellitus and the patient is able to use the items herein ordered to manage his/her glycemic control. This order accurately reflects the patient's documented diagnosis, condition, prescribed treatment and testing regimens.

The information contained in this facsimile message contains confidential patient health information intended for the sole use of the individual named above. If you are not the intended recipient listed above, you are hereby notified that any disclosure, duplication or distribution of this information or the taking of any action in reliance on the contents of this transmission without the express written consent of our office is strictly prohibited. If you have received this fax transmission in error, please notify our office immediately at (877) 521-1855.

DME Suppliers Over Time:
CMS sees decreasing number of suppliers as new policies are implemented
Number of DME Suppliers, 2007-2013
120,000
115,000
110,000
105,000
100,000
95,000
90,000
85,000
80,000
2007
2008
2009
2010
2011
2012
2013

American Association for Homecare

Caring that Feels Right at Home

Statement Of The American Association For Homecare Before The Subcommittee On Financial And Contracting Oversight Of The United States Senate Committee On Homeland Security And Government Affairs

Oversight And Marketing Practices Of Durable Medical Equipment Companies

AAHomecare is the national trade association representing the homecare community. AAHomecare represents health care providers and manufacturers that serve the medical needs of Americans who require sleep therapy technologies, oxygen equipment and therapy, mobility assistive technologies, medical supplies, inhalation drug therapy, home infusion, and other home medical equipment, therapies, services, and supplies in their homes. Our membership reflects a broad cross-section of the homecare community including national, regional, and local providers operating in all 50 states. AAHomecare and its members are committed to advancing the value and practice of quality health care services at home.

AAHomecare strongly supports vigorous program integrity activities to protect Medicare and its beneficiaries. We agree that Medicare must be vigilant to ensure that benefit dollars are not diverted to abusive or fraudulent providers. AAHomecare has a long history of supporting program integrity measures to protect Medicare payments for durable medical equipment, prosthetics, orthotic and supplies (collectively, "DMEPOS"), many of which have been incorporated into law or regulation. In addition, AAHomecare has allocated resources to educating DMEPOS suppliers, whether or not they are AAHomecare members, to improve their awareness of the need for them to adopt compliant and ethical business practices. Consequently, the high claims payment error rate for the Medicare DMEPOS program is as troubling to the association as it is to other stakeholders in the Medicare program.

Our statement below identifies the current Medicare framework for paying and auditing DMEPOS claims. It also identifies the steps that association has taken, and continues to take, to work with CMS and other stakeholders to improve the efficiency of Medicare's audit processes and promote compliant and ethical business practices among DMEPOS suppliers.

I. BACKGROUND

CMS contracts with private companies to administer Medicare program functions such as processing and paying claims. Medicare Administrative Contractors (MACs) pay claims, develop local coverage determinations (LCDs), offer provider education, and perform complex medical reviews (*i.e.*, audits) to

1707 L Street NW, Suite 350, Washington, DC 20036
Tel: 202.372.0107 Fax: 202.835.8306 www.aahomecare.org

identify and recover overpayments. MACs are third-party administrators who perform the routine administrative tasks necessary for the day-to-day operation of the program.

CMS engages other contractors in more targeted roles to perform Medicare Integrity Program (MIP) activities. These contractors, known as Medicare Integrity Contractors (MICs), have a narrower scope of work, focusing almost entirely on preventing, identifying, and recovering payments that should not be paid or that were paid in error. These contractors might also engage in extensive data collection and analysis in order to both identify DMEPOS items subject to abuse and target suppliers with aberrant billing practices.

Zone Program Integrity Contractors (ZPICs) and Program Safeguard Contractors (PSCs) are MICs tasked with these benefit integrity functions. ZPICs and PSCs also develop cases for possible civil or criminal investigations. Other contractors perform MIP activities but provide a narrower range of services. All of the contractors can perform complex audits to carry out their duties. ZPICs, PSCs, and DME MACs conduct both pre and post-payment audits. Comprehensive Error Rate Testing (CERT) contractors and Recovery Audit Contractors (RACs) only audit claims post payment, consistent with their more limited scope of work. [1]

II. THE MEDICARE DMEPOS BENEFIT ERROR RATE

The Centers for Medicare and Medicaid Services (CMS) is required by the Improper Payments Information Act (IPIA) of 2002 to identify improper Medicare payments, compute a national claims payment error rate for the Agency, and develop strategies to reduce and collect improper payments. CMS engages CERT program contractors to calculate the payment error rate for each Medicare benefit, including DMEPOS. CERT contractors perform post-payment audits of claims selected randomly on the date of submission to determine whether the affiliated contractor properly adjudicated the claim.

Prior to 2009, CERT contractors followed Medicare contractor instructions to use "clinical judgment" in conducting audits. That is, contractors were required to employ clinicians to perform audits and the clinicians were, in turn, required to use their clinical expertise to evaluate the medical necessity of equipment or services *in light of the beneficiary's claim history*. Specifically, the Medicare Program Integrity Manual (PIM), effective in 2008, stated as follows:

> During complex review, nurse and physician reviewers may call upon other health care professionals (e.g., dieticians, and physician specialists) for advice. Any determination must be documented and include the rationale for the decision. While MR [medical review] staff must follow national coverage determinations and local coverage determinations, ***they are expected*** to use their expertise ***to make clinical judgments*** when making medical review determinations. ***They must take into consideration the clinical condition of the***

[1] CMS employs contractors to administer the comprehensive error rate testing program (CERT). These contractors audit the MACs to determine their claims payment accuracy. CMS also has contracts with Recovery Audit Contractors (RACs) that work on contingency to recover improper payments that other CMS contractors have not identified.

beneficiary as indicated by the beneficiary's diagnosis and medical history when making these determinations. For example, ***if a medical record indicates that a beneficiary is a few days post-op for a total hip replacement and femur plating, even though the medical record does not specifically state that the beneficiary requires the special skills of ambulance transportation, MR nurses and physicians must use their clinical knowledge to conclude that ambulance transportation is appropriate under such circumstances.***

In 2009, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published a report that was critical of CMS' clinical judgment review policy, holding that CMS misstated the error rate because the Agency did not require contractors to adhere strictly to its coverage and documentation policies. Reacting to the OIG's input, CMS adopted new auditing practices. Under this new formulation of CMS' medical review policy, the Medicare DMEPOS error rate shot up from 10.2% to 51.9% because the bar for documenting medical necessity had increased. Since then, the Medicare error rate for DMEPOS has continued to climb to where it now is at level that has many reasonable people questioning the efficiency and reliability of CMS' approach to payment audits.

It is important to remember that the high error rate is not indicative of rampant fraud among DMEPOS providers. Rather it is a reflection on Medicare's emphasis on technical documentation issues. In other words, the beneficiary has a documented medical need for the equipment or supply, but because the documentation of medical necessity does not meet contractors' heightened technical requirements, auditors determine that claims were improperly paid. Restoring the audit contractors' ability to use clinical review judgment would bring the down what we believe to be an artificially high payment error rate.

III. MEDICARE OVERSIGHT OF CONTRACTORS' AUDIT ACTIVITIES IS FRAGMENTED AND UNWIELDY

As noted above, Medicare contracts with private entities, MAC, CERTS, RACS and ZPICS, to perform payment and audit activities on behalf of the Medicare program. There are four MACs, a CERT, seven ZPICS as well as a number of RACs. As a result of the number of audit contractors with jurisdiction to audit DME claims, DME providers do not have a good understanding of who the contractors are or the reasons underlying the audits they perform. For example, many DME providers do not understand that the CERT contractor's role is to determine the Medicare error rate or that the error rate drives the MACs pre and post payment audits.

The Jurisdiction B MAC provides a typical example. In the 3rd quarter of 2011, the contractor reported an astonishing 93 percent error rate for support mattresses. However, the contractor's analysis shows that 20 percent of the DME providers audited did not respond to the additional documentation requests (ADRs). Notably, the high rate of non-responders improperly skews the DMEPOS error rate upwards. Excluding non-responders from the error rate calculation would result in a more accurate measure. DME providers who do not respond to audit requests require more targeted education. Chronic non-responders raise a red flag and should, at a minimum, receive an onsite visit to make sure they are legitimate DME providers.

IV. AAHomecare's Activities To Promote Compliance And Ethical Business Practices Among DMEPOS Providers

As noted above, AAHomecare strong program integrity measures to ensure that improper claims are not paid and those that are paid are promptly recovered. In addition to our recommendations for streamlining and improving the efficiency Medicare audit processes, AAHomecare has made recommendations that have adopted by Congress or CMS. For example, AAHomecare has been a strong advocate for mandatory accreditation of DMEPOS providers and meaningful quality and service standards for equipment and suppliers. AAHomecare has supported stronger supplier standards, including mandatory site visits for all new suppliers enrolling in Medicare and suppliers renewing their enrollment.

Currently DMEPOS suppliers must be accredited in order to obtain a Medicare billing number, and they must adhere to quality standards promulgated by CMS and administered by the accrediting bodies. Importantly, suppliers must be accredited to furnish the equipment and services they provide to beneficiaries. This means that a supplier that furnishes oxygen must demonstrate to the accrediting body that it meets the standards applicable to oxygen. Likewise, a supplier that furnishes power wheelchairs must be accredited to do so. Providers may furnish only the products and services that they are accredited to furnish.

AAHomecare believes that a more stringent enrollment process, including additional unannounced site visits for suppliers that are new to Medicare as well as close monitoring of their claims submission patterns will help Medicare end the relentless "pay and chase" cycle that has permitted "fly by night" companies to bill Medicare fraudulently and disappear.

In addition, AAHomecare promotes the need for DMEPOS suppliers to adopt ethical and compliant business practices that focus on a company's interactions with beneficiaries, payers and referral sources. AAHomecare has a voluntary Code of Business Ethics that identifies the types of compliant and ethical business practices that supplier's should adopt within their organizations. AAHomecare's goal is for every DMEPOS supplier to understand the importance of promoting a culture of ethics and compliance within their companies. The AAHomecare Code reinforces the need for suppliers adhere to quality standards when they furnish DMEPOS services to all patients. The Code also highlights the importance of understanding payers' coverage, documentation and reimbursement policies and adopting internal policies to prevent, identify and promptly resolve billing errors.

AAHomecare is also committed to assisting DMEPOS suppliers in their efforts to comply with Medicare documentation and billing requirements. AAHomecare members who are experts in Medicare billing, compliance and documentation practices have developed documentation tools for equipment and supplies that are audited frequently and have high payment error rates. These documentation tools are derived from the applicable Medicare coverage policy for the equipment or supply item and highlight specific clinical issues that must be documented the medical record to support the medical necessity the item.

V. CONCLUSION

AAHomecare is concerned about the high Medicare claims payment error rate for DMEPOS. The error rate can be attributed, at least in part, to Medicare contractors' highly technical interpretation and application of Medicare medical necessity requirements and the fragmented nature of CMS' oversight of its payment and audit contractors. Streamlining the audit process and allowing contractors to use clinical judgment when they perform audits will reduce the high claims payment error rate for DMEPOS.

AAHomecare is also committed to eliminating fraud and abuse from the Medicare DMEPOS benefit. The association has consistently supported measures to strengthen Medicare program integrity and increase the scrutiny of DMEPOS suppliers when they enroll in Medicare for the first time. Finally, AAHomecare is committed to promoting compliant and ethical business practices throughout the DMEPOS industry. The AAHomecare Code of Business Ethics addresses suppliers' interactions with patients, payers and referral sources and highlights suppliers' obligation to understand and follow payers' coverage, documentation and billing requirements. To that end AAHomecare has developed documentation tools that suppliers can use in their businesses to improve the quality of their billing practices.

1707 L Street NW, Suite 350, Washington, DC 20036
Tel: 202.372.0107 Fax: 202.835.8306 www.aahomecare.org

MED-CARE DIABETIC & MEDICAL SUPPLIES INC.
933 CLINT MOORE ROAD
BOCA RATON, FL 33487
800-407-0109

March 31, 2014

The Honorable Senator Claire McCaskill
Senate Homeland Security Subcommittee on Financial and Contracting Oversight
Senate Hart Building, Rm 601
Washington, DC 20510
(202) 224-4462

Dear Senator McCaskill,

Thank you for the opportunity to appear before your Committee last year, and to address any follow-up questions resulting from my testimony. Pursuant to your request, these responses reflect figures from April 2013 when the questions were posed. In regards to questions 2 & 3, Med-Care's legal counsel has advised that we need a HIPAA waiver in order to provide the patient specific information requested therein. We know it is extremely important to protect patient privacy in these matters. We are prepared to promptly share this information with you once you receive and transmit the waiver. With respect to the other questions that arose during the hearing, please find Med-Care's responses below.

1. Provide the percentage of Med-Care's business that services Medicare Part D beneficiaries.

ANSWER: Med-Care cannot completely dissect this percentage of all Part D payments due to our various payments sourcing, with some Part D payments coming from Medicare PBMs which also process claims for private pay patients. However, to the best of our ability, the percentage is less than 10%.

4. Provide the percentage of Med-Care's business that comes from calls made to Medicare seniors from the numbers on Med-Care's website

ANSWER: Med-Care has a multifaceted marketing strategy which includes use of radio, mail, referrals, as well as multiple entry point to their website. Due to this mix, it is difficult to determine exact number of calls that originated from their website. With that in mind, we believe the percentage would be approximately 80%.

MED-CARE DIABETIC & MEDICAL SUPPLIES INC.
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800-407-0109

5. The percentage of the $35 million Med-Care received from CMS in 2012 that came from Med-Care orders for equipment initiated by doctors.

ANSWER; Each order for equipment is pursuant to a physician's order. Nothing is sent or filled without that consent. Absent this order from a physician, we cannot bill Medicare nor private insurance for the equipment. Physicians have wide discretion in this process as they can refuse to sign this order if they do not believe Med-Care should deliver supplies to their patients. The Med-Care business model is built to market to the patient, thus avoiding some of the safe-harbor pitfalls that can result from direct physician marketing. However, the physicians ultimately have the final word. Given all of this, the percentage that is initiated by a physician is approximately 5% but the percentage that is authorized by a physician is 100%.

6. The percentage of the $35 million Med-Care received from CMS in 2012 that came from Med-Care orders for equipment initiated by patients.

ANSWER: As we previously stated our business plan and marketing practices, which have been approved by CMS, are based on a consumer focused model. However, a consumer/patient cannot initiate a request until a physician has authorized the need for medical supplies with a prescription. Even with this prescription, the patient's physician must authorize the order (see above answer). The result is that approximately 95% of the 2012 revenue estimate came from the patient's choice to use Med-Care, but again, 100% of the orders were authorized by a physician.

I hope my answers and my testimony are helpful to the subcommittee's review of these issues. We appreciate the opportunity to assist in your oversight of the Medicare program.

Sincerely,

Dr. Steven R. Silverman
President

Follow-up clarifications to March 31, 2014 responses:

Q: What's the breakdown of the percentage of Med-Care's business from the various points of entry (radio, mail, referrals, website inquiries, phone call inquiries)?

A: approximately 75% from the website directly, 10% from direct mail responses, 8% patient referrals, 5% physician referrals and 2% from radio advertising.

Q: What's the percentage of orders that were initiated by patients? Although a patient may ultimately choose to use Med-Care, this doesn't shed light on whether the initial contact was initiated by the patient.

A: As a direct to consumer business, much of Med-Care's communication is directly to and with the patient. There are about 5% of orders that are directly initiated by a physician on behalf of the patient, but 95% of the initial contact with a patient is patient initiated, after receiving a script from their doctor.

TO: Senate Committee on Homeland Security and Governmental Affairs, subcommittee on Financial and Contracting Oversight

FROM: Med-Care Diabetic and Medical Supplies, Inc.

RE: Med-Care Diabetic and Medical Supplies, Inc. and Ms. Sandra Pariseau

DATE: 07/01/2014

The Senate Committee on Homeland Security and Governmental Affairs, subcommittee on Financial and Contracting Oversight held a hearing held May 22, 2013 entitled "Oversight and Business Practices of Durable Medical Equipment Companies". During this hearing, Senator Claire McCaskill indicated that Medicare beneficiary Ms. Sandra Pariseau claimed that she never asked Med-Care for a prescription and that she then received a letter from Med-Care stating that her Sleep Apnea prescriptions have been approved. (Hearing Transcript -P. 19-20 lines 23-25; lines 1-5). The Senator further indicated that "... from [Pariseau's] perception, [Med-Care] knew her doctor, [Med-Care] knew her prescription, this is what she's telling us. . . [Med-Care] knew her doctor, [Med-Care] knew her prescriptions, and then she started getting letters that she needed to sign off on her new sleep apnea machine." (Hearing Transcript – P. 24-25, lines 23-25, lines 1-5)

At the hearing, Dr. Steve Silverman, President of Med-Care Diabetic and Medical Supplies testified to the contrary. Dr. Silverman agreed to provide relevant documentation regarding Ms. Pariseau subject to the Senator's office obtaining a HIPAA waiver from Ms. Pariseau authorizing the release of such information. The subcommittee subsequently obtained the HIPAA waiver from Ms. Pariseau dated (insert date) and requested that Med-Care provide additional explanation and documentation to support Med-Care's testimony.

The purpose of this Memorandum is to provide the additional clarification and information the Committee requested with respect to Dr. Silverman's testimony and Med-Care's interaction with Ms. Sandra Pariseau.

RESPONSE

As Dr. Silverman testified at the hearing, Med-Care Diabetic and Medical Supplies, Inc. does not buy patient lists or initiate unsolicited calls to prospective customers/Medicare beneficiaries. Individuals must affirmatively request that Med-Care contact them regarding medical supplies as well as provide Med-Care with the name of their treating physician. In fact, Med-Care has a standard marketing protocol which is CMS approved and the company has implemented with respect to marketing Durable Medical Equipment to prospective customers, including Medicare beneficiaries (see Attachment A).

Attachment B is the "Consent Guard Certification" which is generated by Med-Care's IT system as they receive new customer inquiries from their website. This certification indicates that Ms. Sandi Pariseau requested information regarding Sleep Apnea products on December 8, 2012 at 10:00 pm. This certification notes the time, the URL, the remote IP address and the geographic

location of that IP address. In addition, this certification records the information that is affirmatively inputted by the individual, including their name, address, phone number, email address and their date of birth.

As further evidenced by Med-Care's standard internet marketing intake form accessed via the web at http://medcareinc.com/sleep-apnea.aspx (see Attachment C), each advertisement includes a box that must be affirmatively checked that gives express written consent authorizing Med-Care to contact them via telephone regarding medical supplies. Please note that the new standard form no longer requests information regarding the date of birth in order to provide an added layer of identity protection for individuals access Med-care's site.

As Dr. Silverman further testified at the hearing, in order to obtain information regarding an individual's personal physician, a customer account representative must speak with that individual directly. Hence, after providing her contact information to Med-Care via the internet on December 8, 2012, a Med-Care customer account representative contacted Ms. Pariseau to obtain her physician's information and her consent to contact the doctor's office to obtain a new prescription for Medicare supplies needed to treat her sleep apnea. Contrary to allegations made at the hearing, it was during this call that Ms. Pariseau provided Med-Care with the name of her personal physician, Dr. Lee Wesler.

After the call with Ms. Pariseau in which she provided her treating physician information and per Med-Care customer protocol, Med-Care sent a "Welcome Letter" to Ms. Pariseau (see Attachment D), stating "based on your conversation with one of our intake professionals, your sleep apnea supply prescriptions have been sent" to "Dr. Lee Wesler". The letter further states that Med-Care will not ship any products until Ms. Pariseau's physician has provided the required prescription and they have followed up with her again to confirm that she still wants the supplies. This is another proactive safeguard implemented by Med-Care which ensures that supplies are not provided unless the patient wants them.

In addition to the Welcome Letter, Ms. Pariseau was provided a letter required by CMS which outlines options for acquiring a new sleep apnea machine which she was eligible to receive in addition to her sleep apnea supplies (see Attachment E).

According to the Med-Care "Patient Comments Report" (see Attachment F), Med-Care obtained Ms. Pariseau's physician information and subsequently, made 2 attempts to obtain a valid prescription from her physician, Dr. Lee Wesler. On 2 occasions (12/18 and 12/19), the physician signed prescriptions for sleep apnea supplies and faxed these prescriptions to Med-Care for processing; however, the physician neglected to date both of these prescriptions. The comment report indicates that ultimately Med-Care obtained verbal verification of the date that the prescription was signed. It is also important to note that even though Ms. Pariseau was eligible by Medicare rules for a new sleep apnea machine in addition to her supplies, Med-Care did not attempt to send or obtain a prescription for anything more than what Ms. Pariseau requested, which was only the supplies.

Med-Care's Personal Patient Advocate subsequently tried to follow up with Ms. Pariseau, per the CMS standard protocol, to determine whether she still wanted the supplies but was unable to

reach Ms. Pariseau. Therefore, Ms. Pariseau received a letter dated 12/20/12 (see Attachment G) from Med-Care asking Ms. Pariseau to call them if she wanted the supplies. The Patient Comment Report further documents that Med-Care spoke to Mr. Pariseau on 3/6/13, and at that time Ms. Pariseau informed Med-Care that she decided to stay with a local supplier. Thereafter, Ms. Pariseau's account was closed and no further action was taken.

Ultimately, no supplies were ever shipped and Med-Care did not charge Ms. Pariseau or Medicare for any supplies.

Attachment A

MARKETING FLOW CHART

1. User signs up to be contacted by Med-Care Diabetic and Medical Supplies, Inc. ("Med-Care") online. The beneficiary is signing up to be contacted regarding a Medicare covered item.
    a. The advertisement clearly states that the user is giving Med-Care consent to contact them via telephone.
    b. The patient will receive an email in real time. This will further inform the patient that Med-Care will be calling them. The patient will also be given the opportunity to place their phone number on our internal Do Not Call lists and therefore opt out from telephone contact.
    c. We validate the address and phone number before the person is to be called. We remove any found invalid submissions.

2. When a beneficiary fills out an online form we capture the information they submit in the form. The information is stored in our database. We also retain the date/time of when the beneficiary signed up, remote IP address, and details that show which type of advertisement and what website the beneficiary may have been on when they clicked our advertisement. We can reference every submission that was made to our advertisements at any given time.
    a. For the initial conversation with the beneficiary we maintain telephone records of the initial enrollment.
    b. For any product shipment calls involving a patient advocate we document the conversation in the beneficiary's medical records.
    c. All of these records are maintained on our own proprietary secure server that can be accessed by Med-Care at any time.

3. A Med-Care representative then contacts the patient to enroll them.
    a. All representatives are W2 Med-Care employees. We do not employ third party enrollment call centers.
    b. Our phone system is in compliance with all FCC rules. We maintain internal Do Not Call lists.

4. After enrollment we check to make sure the beneficiary's insurance information is active. If the insurance is active and we can service the patient we then send out a welcome packet in the mail.
    a. Welcome packet includes information about the enrollment process.
    b. Also included is all of our contact information, a patient bill of rights, rent purchase agreement, and other relevant information for new patients.

5. A phone call to the patient's physician is made to verify their contact information. We then fax a doctor's order over to the physician for the supplies that the patient requested.

6. When a valid doctor's order is returned the patient receives a call from a Med-Care patient advocate to go over the order. All orders are authorized by the beneficiary before they are billed or shipped.
    a. The patient advocate will verify the complete order. They are responsible for going over insurance benefits, product detail, confirming the physician's order and their mailing address.
    b. The patient advocate will answer any beneficiary questions.
    c. Absolutely no orders are shipped until they are cleared by a patient advocate.

Attachment B

Consent Guard Certification

Certficate ID: 2564aec2-72ae-4970-889b-3b3a5f082ccd

When did they visit?

Visit Date	12/8/2012
Visit Time	10:00 PM

Where did they visit?

Page URL	Unknown Source URL
Snapshot URL	https://guardian.medcareinc.net/2564aec2-72ae-4970-889b-3b3[redacted]

Who visited?

Remote IP Address	70.233.84[redacted]
Geographic Location (Approximate)	Shelton, CT
Browser	Unknown
Operating System	Unknown

What did they submit?

Below is the data that was collected from the consumer when they filled out the form.

FirstName	SANDI
LastName	PARISEAU
Address	[redacted]
City	Pomfret Center
State	CT
Zipcode	06259
Phone	[redacted]
Alternate Phone	Not Submitted
Email	[redacted]
Date of Birth	[redacted]
Product	Sleep Apnea

Attachment C

Speak with an advocate to see if you qualify for new CPAP/BiPAP Machines

First Name *

Last Name *

Phone *

Email *

I am an existing patient.

By submitting I give express written consent authorizing Med-Care Diabetic & Medical Supplies to contact me by telephone (including calls from an automated telephone dialing system) regarding diabetic, nebulizer, cpap, ostomy, oxygen, catheter and wound care supplies. I understand that I am not required to provide my consent as a condition of purchasing any products or services.

or call us today at
1.888.777.0737

Submit

Sleep Apnea Supplies

Med-Care's sleep apnea supply program will help you have a deeper and safer night sleep. Med-Care delivers CPAP/BiPAP Machines, all masks, and related supplies. We offer new non-intrusive masks and nasal pillows. Med-Care will help you avoid risks associated with obstructive sleep apnea with our state of the art supplies.

Sleep apnea is a serious sleep disorder that occurs when a person's breathing is interrupted during their sleep. People with untreated sleep apnea can stop breathing repeatedly in their sleep which can cause a stop in oxygen flow to the body and brain.

Fill out this form or call now to speak with one of our highly trained medical experts. We are standing by to assist you.

If you have Medicare or private insurance you may qualify to receive these items shipped to your home with no out of pocket cost to you.*

*Co-payments, deductibles and some restrictions may apply.

For information regarding the proper methods of disposing unused medicines, please visit the FDA Website.

- DIABETIC TESTING SUPPLIES
- RESPIRATORY SUPPLIES
- CATHETER/OSTOMY SUPPLIES
- OXYGEN SUPPLIES
- ORTHOTIC/E.D. SUPPLIES
- SLEEP APNEA SUPPLIES
- DIABETIC SHOES
- WOUND CARE
- LYMPHEDEMA SUPPLIES
- PAIN MANAGEMENT
- NEUROPATHY SUPPLIES

Attachment D

MED-CARE DIABETIC & MEDICAL SUPPLIES, INC.
933 CLINT MOORE ROAD
BOCA RATON, FL. 33487
Phone: (888) 777-0737

TEMP RETURN SERVICE REQUESTED

Date: 12/19/12

REDACTED

SANDRA PARISEAU

, CT

Welcome to our Sleep Apnea Supply Program.

SANDRA PARISEAU,

Congratulations and Welcome to Med-Care Diabetic & Medical Supplies sleep apnea supply program. Your insurance has been accepted and your free membership has been approved! Med-Care has been a nationally recognized provider for Medicare, Medicaid and over 1,000 private insurance companies since 1999. We are dedicated to assisting our patients with their needs, while providing the nation's best service available.

Based on your conversation with one of our intake professionals, your sleep apnea supply prescriptions have been sent to the following physician:

Dr. [redacted]

REDACTED

If the physician above is not your correct physician, please call customer service at (888) 777-0737.

When we receive your prescription, your Personal Patient Advocate will contact you. They will answer any questions you may have regarding our program, your forthcoming order and supplies, the documents you received in this package, as well as any other questions you may have. We will not ship any products until you have received this call and spoken to us personally. The number we have to reach you is . If this is not the correct number, please call us immediately.

Our Mission is clear;

- Provide the highest quality of service
- Offer premium products
- Save our members as much money as we can
- Support members with counseling and informative newsletters

Please visit our website at http://www.medcareinc.com or call us anytime.

Together with Med-Care,
Let's Live a Healthier and Better Life!
Med-Care Diabetic and Medical Supplies Inc.

Attachment E

MED-CARE DIABETIC & MEDICAL SUPPLIES, INC.
933 CLINT MOORE ROAD
BOCA RATON, FL. 33487
Phone: (888) 777-0737

Date: 12/19/12

REDACTED
SANDRA PARISEAU

, CT .

SANDRA PARISEAU,

I received instructions and understand that Medicare defines the _____ item that I will be receiving as being either a capped rental or an inexpensive or routinely purchased item.

____ FOR CAPPED RENTAL ITEMS:

- Medicare will pay a monthly rental fee for a period not to exceed 13 months, after which ownership of the equipment is transferred to the Medicare beneficiary.
- After ownership of the equipment is transferred to the Medicare beneficiary, it is the beneficiary's responsibility to arrange for any required equipment service or repair.
- Examples of this type of equipment include:
  Nebulizers, Continuous Airway Pressure (CPAP) Devices.

____ FOR INEXPENSIVE OR ROUTINELY PURCHASED ITEMS:

- Equipment in this category can be purchased or rented; however, the total amount paid for monthly rentals cannot exceed the fee schedule purchase amount.
- Examples of this type of equipment include:
  Home Blood Glucose Monitors, Walkers, and Seat Lift Mechanisms.

I understand that unless otherwise stated I will be renting the Capped Rental items and purchasing the Routinely Purchased items above.

If you would like to opt out, please contact us before your shipment is sent,
at 888-777-0737 or select below:

Purchase Option _____ Rental Option _____

Thank You and we look forward to supplying you!

_____ _____
Beneficiary Signature Date

Attachment F

Printed On: 03/27/2014
02:23 PM

MEDCARE DIABETIC

Page Number

Patient Comments Report

Pat Id.	Patient Name	Address	City / State / Zip
8927631	PARISEAU, SANDRA	[redacted]	POMFRET CENTER, CT, 06259

Primary Insurance	Policy #	Secondary Insurance	Policy #
MCARE-A	[redacted]		

Phy Id.	Physician Name	Pat Birthday	Pat Type
[redacted]	[redacted]	[redacted]	LC

Date	User ID	Comment Line
12/18/2012	LEA	RECD FF/NP/NAS RX WITH NO DATE ------->PLACED IN EVE FODLER TO GET A VALID RX
12/18/2012	EVE	MANUALLY FAXING RX FOR SIGNATURE & DATE
12/19/2012	LEA	RECD DUP FF/NP/NAS RX WITH NO DATE --------> PLACED IN EVE FOLDER TO GET A VALID RX
12/19/2012	MIS	YES CMN E0601-INT;04/17/2002 LON;15LBD;01/17/2003 MP;10
12/19/2012	EVE	MANUALLY FAXING RX FOR SIGNATURE & DATE
12/19/2012	LEA	REC DDUP FF/NP/NAS RX WITH NO DATE 0-------->PLACED IN EVE FOLDER
12/19/2012	EVE	SPK TO LISA S. MEDICAL RECPT, GAVE VERBAL OK 12/19/12. CHANGED TYPE TO POK FROM CRX
12/20/2012	LEA	SCANNED IN UPDATED FF/NP/NAS RX
03/06/2013	NOZ	SP TO PT SANDRA, PT DECIDED SHE IS STAYING WITH LC

Total comments 9

Attachment G

MED-CARE DIABETIC & MEDICAL SUPPLIES INC.
933 CLINT MOORE ROAD
BOCA RATON, FL 33487
Phone: (888) 492-3701

TEMP RETURN SERVICE REQUESTED

SANDRA PARISEAU
)

CT ·

ID#

REDACTED

Date: 12/20/2012

Dear SANDRA PARISEAU,

We have been unable to reach you with regard to your sleep apnea supplies. Our company is currently holding your prescription from Dr. LEE WESLER. We need to speak with you as soon as possible to ship your order. Please call us at (888) 492-3701 today so we may send you your requested supplies.

We have been trying to reach you at ·, please call us now at
(888) 492-3701.

Thank you and we look forward to hearing from you,

Med-Care Diabetic & Medical Supplies Inc.
933 CLINT MOORE ROAD
BOCA RATON, FL 33487
Phone: (888) 492-3701

Post-Hearing Questions for the Record
Submitted to Peter Budetti
From Senator Claire McCaskill

"Durable Medical Equipment Companies Business Practices"
April 24, 2013

Chairwoman McCaskill

The estimated improper payment rate for durable medical equipment was approximately 66% in 2012. By comparison, the overall estimated improper payment rate for Medicare fee-for-service was 8.5% in 2012. You acknowledged during the hearing that the estimated improper payments for durable medical equipment represented a crisis for potential fraud and abuse by durable medical equipment suppliers and substantial costs to the taxpayer, but argued that improper payments may be attributed to several factors including technical errors as well as potential fraud.

1. **What is the total estimated dollar amount and percentage of estimated improper payments that were made as a result of potential fraud or abuse in 2011? In 2012?**

Answer: Under the Improper Payments Information Act of 2002, as amended, and OMB's implementing guidance, agencies are required to establish annual error rate measurements and corrective action plans for programs susceptible to significant improper payments. CMS developed the Comprehensive Error Rate Testing (CERT) program to calculate the Medicare FFS program improper payment rate, which is reported in the DHHS Agency Financial Report, CMS Financial Report, and on www.paymentaccuracy.gov. The CERT program cannot label a claim fraudulent. The CERT program measures the improper payment rate, not the rate of fraud.

The IPIA and the OMB implementing guidance defines "improper payment" as payments that should not have been made, payments made in an incorrect amount (including both overpayments and underpayments), payment to an ineligible recipient, payment for an ineligible service, any duplicate payment, payment for services not received. HHS uses the same definition for the CERT program. To calculate the error rate, claims are selected randomly from all Medicare FFS claims to determine if they were paid properly under Medicare coverage, coding, and billing rules. If these criteria are not met, the claim is counted as either a total or partial improper payment. The CERT program uses random claim selection, and CMS collects medical records for the claims in the sample. Reviewers are often unable to see provider billing patterns or trends that may indicate potential fraud when making payment determinations.

There are various causes of improper payments – for example, payment for services where the supporting documentation submitted did not support the ordered service. While all payments stemming from fraud are considered "improper payments," not all improper payments constitute

fraud. In order to reduce improper payments, CMS' program integrity activities target the range of causes of improper payments, and as part of its comprehensive approach, the Center for Program Integrity coordinates with other components across CMS.

Reducing the DME error rate is a key priority for CMS, and CMS is taking a number of steps to improve payment accuracy for DME. To achieve this goal, CMS implemented a demonstration on prior authorization for Power Mobility Devices, began using competitive bidding to reimburse suppliers at market rates, required enhanced screening for DME suppliers to root out bad actors, and strengthened our partnership with law enforcement.

2. **What is the total estimated dollar amount and percentage of estimated improper payments that were made as a result of potential technical errors in 2011? In 2012?**

Answer: CMS developed the CERT program to calculate the Medicare FFS program improper payment rate, and CERT defines an improper payment as a paid claim that should have been denied or paid at another amount (including both overpayments and underpayments). Based upon the review of the medical records, claims identified as containing improper payments are categorized into one of five error categories, which are described below.

- No Documentation—Claims are placed into this category when either the provider fails to respond to repeated requests for the medical records or the provider responds that they do not have the requested documentation.
- Insufficient Documentation—Claims are placed into this category when the medical documentation submitted is inadequate to support payment for the services billed. In other words, the medical reviewers could not conclude that some of the allowed services were actually provided, provided at the level billed, and/or the services were medically necessary. Claims are also placed into this category when a specific documentation element that is required as a condition of payment is missing, such as a physician signature on an order, or a form that is required to be completed in its entirety.
- Medical Necessity—Claims are placed into this category when the medical reviewers receive adequate documentation from the medical records submitted and can make an informed decision that the services billed were not medically necessary based upon Medicare coverage policies.
- Incorrect Coding—Claims are placed into this category when the provider or supplier submits medical documentation supporting (1) a different code than that billed, (2) that the service was performed by someone other than the billing provider or supplier, (3) that the billed service was unbundled, or (4) that a beneficiary was discharged to a site other than the one coded on a claim.
- Other— Claims are placed into this category if they do not fit into any of the other categories (*e.g.*, duplicate payment error, non-covered or unallowable service).

In 2012, the Medicare FFS improper payment rate was 8.5 percent, totaling $29.6 billion[1]. This is a slight decrease from the 8.6 percent improper payment rate reported in 2011. As part of the annual error rate measurement, CMS also identifies error rates for some specific parts of the programs, including DME. In 2012, the improper payment rate for DME was 66 percent and DME remains a focus area for CMS.

Through our predictive analytics technology, DMEPOS competitive bidding, and demonstration projects such as the one for the prior authorization of power mobility devices, CMS is working to prevent improper payments and reduce incentives to conduct DME-related fraud.

3. **In 2012, how many criminal fraud prosecutions resulted in conviction related to durable medical equipment? How many resulted in plea agreements or other agreements in lieu of prosecution? How many civil actions resulted in judgments in favor of the government? How many resulted in settlement agreements or other agreements in lieu of final resolution by the courts? Please provide the amount of money recovered for each category.**

Answer: While criminal fraud prosecutions are the responsibility of the Department of Justice (DOJ), CMS works closely with DOJ to combat fraud. In FY 2012, the interagency Medicare Strike Force accomplishments in the nine Strike Force cities (Miami, FL; Los Angeles, CA; Detroit, MI; Houston, TX; Brooklyn, NY; Baton Rouge, LA; Tampa, FL; Chicago, IL; and Dallas, TX) included 117 indictments; information and complaints involving charges filed against 278 defendants who allegedly collectively billed the Medicare program more than $1.5 billion; 251 guilty pleas negotiated and 13 jury trials litigated, with guilty verdicts against 29 defendants; and imprisonment for 201 defendants sentenced during the fiscal year, averaging more than 48 months of incarceration. While these figures include multiple types of fraud, examples of successful actions related to durable medical equipment are available in the FY 2012 annual report on the Health Care Fraud and Abuse Control Program.[2]

In your testimony, you stated that, in 2011, "Medicare DME spending totaled $7.8 billion, down 6 percent from $8.3 billion in 2008." Later in your testimony, you reference the "Medicare Fee-for-Service 2011 Improper Payments Report" which states that the total paid amount for Durable Medical Equipment was $9.7 billion. The 2011 CMS Statistics report states that FY 2011 benefit payments for durable medical equipment were $8.5 billion.

4. **Why does CMS have three different totals for DME spending in 2011?**

[1] http://www.paymentaccuracy.gov/programs/medicare-fee-service.

[2] http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2012.pdf. Pages 28-30.

Answer: Differences in CMS' reporting of total DME spending relate to the data set used to estimate total spending and assumptions made. Factors that might change the estimated total spending amount include which beneficiaries are included in the calculation, whether beneficiary cost sharing is included, and the reporting period, among other factors. For example, the data used in the statement that in 2011, "Medicare DME spending totaled $7.8 billion, down 6 percent from $8.3 billion in 2008," is from the Geographic Variation Public Use File.[3] This data reports spending at the hospital referral region level and is used to evaluate geographic variation in the utilization and quality of health care services for the Medicare fee-for-service (FFS) population. Data from CMS' Office of the Actuary, in the 2011 CMS Statistics Report, makes different assumptions about the Medicare FFS population, resulting in an estimated benefits payments total of approximately $8.5 billion for FY 2011.[4] The Medicare FFS 2011 Improper Payments Report (CERT report) reports DME spending in the reporting period of July 1, 2010 to June 30, 2011, so it does not align with other data on CY 2011 or FY 2011 expenditures. Importantly, the CERT report extrapolates total DME spending based on the sample of claims it uses to calculate the DME error rate, and is not intended to be used as actual spending data.

5. **Exactly how much did CMS pay for durable medical equipment in 2011?**

Answer: DME benefit payments in FY 2011 totaled approximately $8.5 billion.[5]

One of the companies invited to testify at the hearing by the subcommittee is Med-Care Diabetic and Medical Supply. An individual who contacted the Subcommittee about problems patients experience with durable medical equipment suppliers explained that many companies have names that sound over the phone very similar to Medicare or another U.S. government agency that patients may mistake as being a part of the federal government.

6. **Under current law, what authority exists to prevent durable medical equipment supply companies from using names that are similar to Medicare or other federal government programs or agencies?**

Answer: Under section 1140 of the Social Security Act, individuals or organizations may be subject to a civil money penalty for the misuse of words, symbols, or emblems or names in reference to Social Security or Medicare. If individuals have information about suppliers or others who are misusing CMS words, symbols, or emblems, they should contact the HHS Office of Inspector General.

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[3] http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/index.html.

[4] See Table III.6 in 2011 Expenditure table, available through http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ResearchGenInfo/CMSStatistics.html.

[5] Ibid.

The Subcommittee has received information from patients and doctors who allege that durable medical equipment suppliers are harassing patients and inundating doctors with medical supply order forms which have not been requested and in some instances can result in increases in the amount of unnecessary medical equipment claims paid by Medicare.

7. **Does the government have the authority under current law to impose a requirement that a request for durable medical equipment originate from the doctor and not from pre-generated forms sent to doctors by a third party? If no, what authorities would be required? If yes, would CMS consider imposing such a requirement?**

Answer: Under current law, Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) must be ordered by a physician or practitioner enrolled in Medicare. A supplier must have an order from the treating physician or practitioner stating the beneficiary needs the item before the supplier may dispense any DMEPOS item to the beneficiary.[6]

While CMS does not have the legislative authority to regulate or ban supplier generated forms, we do not rely solely on supplier documentation. A supplier-prepared statement by itself does not provide sufficient documentation of medical necessity, even if it is signed by the treating physician or supplier. There must be information in the beneficiary's medical record to support the medical necessity for the item, and the treating physician or practitioner's medical records must substantiate the information on a supplier-prepared statement.[7]

CMS neither prohibits nor endorses the use of templates to facilitate record keeping. However, CMS discourages the use of templates that provide limited options and/or space for the collection of information. Templates that use check boxes, predefined answers and limited space to enter information often fail to capture sufficient clinical information to demonstrate that all Medicare coverage and coding requirements are met.[8]

CMS believes that the requirement for physician-created documentation as the basis for medical necessity of DMEPOS items will be strengthened by the face-to-face encounter requirements mandated under section 6407 of the Affordable Care Act.

The HHS Inspector General and GAO have found that CMS has failed to recover the overwhelming majority of improper payments for durable medical equipment. CMS instituted surety requirements for suppliers of durable medical equipment in 2011, in part to be able to better recover these overpayments. However, the Inspector General found

[6] Medicare Program Integrity Manual, CMS Internet-Only Manual 100-08, Ch. 5, Section 5.2.1
[7] Medicare Program Integrity Manual, CMS Internet-Only Manual 100-08, Ch. 5, Section 5.7
[8] Medicare Program Integrity Manual, CMS Internet-Only Manual 100-08, Ch. 3, Section 3.3.2.1.1

that CMS has collected just over $263,000 out of over $70 million in overpayments eligible for surety bond recovery. The Inspector General found that 98% of the companies it reviewed had overpayments in excess of $50,000, the current level required for surety bonds.

8. Why hasn't the Secretary increased bond requirements above the current $50,000 level in light of the Inspector General's findings?

Answer: CMS may require a surety bond in excess of $50,000 when information on adverse actions is reported by and/or taken against enrolled suppliers. The National Supplier Clearinghouse (NSC), the CMS contractor that processes Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) enrollment applications, uses this information to determine if an elevated surety bond is appropriate. When an application is received, the NSC determines if the supplier has had an adverse legal action that resulted in a revocation within the past 10 years. If any qualifying revocation was not overturned on appeal and the reenrollment bar has expired, an elevated bond in the amount of $100,000 is required for enrollment.

9. What is CMS doing to recover this money?

Answer: CMS oversees the DME Medicare Administrative Contractors (MACs) which perform these collection activities. The DME MACs are continuing to make requests for payments from sureties, and CMS expects additional overpayments to be collected as a result.

During the hearing, you testified that because of provisions passed in the Affordable Care Act, CMS for the first time has increased fraud detection and prevention capabilities that are helping to reduce costs to the taxpayer in substantial ways. You stated that the Affordable Care Act allows CMS to suspend payment to a business if there is credible information that a particular business is engaged in fraudulent activity and that business cannot receive payment for DME claims until the investigation is complete.

10. Has CMS fully implemented this provision of the Act?

Answer: Yes, on February 2, 2011, CMS published the Final Rule with comment period entitled —Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers (CMS-6028-FC). This rule implemented the Affordable Care Act provision allowing the suspension of payments to a provider or supplier pending the investigation of a credible allegation of fraud and has been in effect since March 25, 2011.

11. How often has CMS used this authority with respect to DME suppliers since it came into effect?

Answer: CMS has imposed 30 payment suspensions on DME suppliers between March 2011 and April 24, 2013.

12. What other fraud and abuse prevention authority has been provided under the Affordable Care Act?

Answer: The Affordable Care Act provides CMS with powerful new anti-fraud tools and allows CMS to focus on preventing fraud before it happens. These new authorities offer more front-end protections to keep those who are intent on committing fraud out of the programs and new tools for deterring wasteful and fiscally abusive practices, identifying and addressing fraudulent payment issues promptly, and ensuring the integrity of the Medicare and Medicaid programs. Specifically, the Affordable Care Act requires CMS to establish risk-based provider enrollment screening measures, which CMS began implementing in March 2011. CMS has embarked on an ambitious project to revalidate the enrollments of all existing 1.5 million Medicare suppliers and providers under the new Affordable Care Act screening requirements. Since March 2011, CMS approved for enrollment nearly 458,435 Medicare providers and suppliers, including 30,105 DMEPOS suppliers, under these enhanced screening requirements of the Affordable Care Act. Because of revalidation and other proactive initiatives, CMS has deactivated 159,449 enrollments, including 24,880 DMEPOS enrollments, and revoked 14,009 enrollments, including 1,753 DMEPOS enrollments.

13. With respect to durable medical equipment suppliers, how much has CMS recovered based on the authority provided under the Affordable Care Act?

Answer: CMS is using many of the new anti-fraud authorities provided in the Affordable Care Act and the Small Business Jobs Act of 2010 to strategically combat fraud, waste, and abuse, and is integrating additional tools into our current program integrity efforts. These new tools and authorities support our comprehensive strategy to prevent fraud and abuse, but are not necessarily resulting in recoveries, because CMS is focused on stopping fraudulent claims from being paid in the first place. For example, CMS has deactivated 24,880 DMEPOS enrollments and revoked 1,753 DMEPOS enrollments from March 2011 to April 2013. While we believe that these actions will protect taxpayer dollars, we are unable to estimate savings at this time.

The DMEPOS competitive bidding program is one of CMS' most powerful tools to reduce DMEPOS spending and provide greater value to the Medicare program, beneficiaries and taxpayers. The program works by establishing Medicare's DMEPOS payments based on competitive market pricing, thereby reducing beneficiary out-of-pocket costs, program outlays, and suppliers' incentive to fraudulently bill Medicare for DMEPOS. It is projected to save the Medicare Part B Trust Fund $25.8 billion and beneficiaries $17.2 billion over ten years.[9] The program is already generating significant savings for the Federal Government and the

[9] FY 2014 Congressional Justification, Page 38. Available at http://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2014-CJ-Final.pdf

approximately 2.3 million Medicare fee-for-service beneficiaries residing in the areas where competitive bidding is in effect. According to CMS' analysis of claims from 2010 and 2011, the competitive bidding program has reduced DMEPOS spending by approximately $202.1 million—or 42 percent overall—in the nine Round 1 Rebid areas.[10] The program has significantly reduced payment amounts, with an average price reduction of 35 percent from the fee schedule.

Under 42 U.S.C. §1395m, CMS has authority to exclude suppliers who violate the telemarketing prohibitions from participation in Medicare.

14. How many times has CMS used that authority?

Answer: If CMS finds a company has inappropriately engaged in telemarketing in violation of the applicable Medicare supplier standard, we may institute appropriate corrective actions including supplier education. The supplier has an opportunity to correct the improper telemarketing behavior. However, if the supplier does not come into compliance, CMS has authority to revoke the supplier's billing privileges and as of April 24, 2013, CMS has revoked one supplier for telemarketing violations. Since then, that supplier submitted a corrective action plan demonstrating that it had come into compliance with Medicare requirements regarding telemarketing.

CMS often finds that when we begin investigating a supplier for improper telemarketing, we find other inappropriate behaviors. CMS may revoke a supplier's billing privileges based upon a number of different reasons, including the violation of one or more other DMEPOS supplier standards, the misuse or abuse of billing privileges, the failure to document properly or for providing false or misleading information. As a part of these efforts, CMS has revoked billing privileges of 1,753 DME suppliers – about 1.75 percent of the total DME supplier universe.

If CMS suspects fraudulent and criminal behavior, CMS can make a referral to law enforcement. For example, in April 2012, a DME supplier paid $18 million to resolve allegations that it submitted false claims for diabetic testing supplies and other DME that was sold to beneficiaries through inappropriate telemarketing.

15. What statutory authorities are needed to expand telemarketing regulations to include e-mail, direct-mail, and modern forms of communication such as text messaging?

Answer: CMS has statutory authority only to regulate unsolicited telephone contacts by DME suppliers.

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[10] Competitive Bidding Update—One Year Implementation Update, available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf

16. What additional statutory authority, if any, would be required to prevent all telemarketing of durable medical equipment to Medicare patients?

Answer: We would be happy to provide technical assistance to the committee on expanding this authority.

In CMS' April 10, 2013, response to the Subcommittee's Request for Information, CMS stated that the Recovery Auditor has reviewed more than 6,100 claims from U.S. Healthcare Supply, LLC and that more than 5,600 of those were found to be improper payments. CMS also stated that the Recovery Auditor has demanded $100,635 in overpayments from this supplier and that most of the overpayments were a result of billing for supplies after a beneficiary's death or billing for supplies while the beneficiary was in a Skilled Nursing Facility.

17. Please provide the most detailed breakdown of what constitutes an "improper payment" that is available from CMS' record keeping. For example, CMS stated that most of the overpayments were a result of two types of incorrect claims – what percentage of the 6,100 sampled claims fall under each type of incorrect claim?

Answer: The Recovery Auditors reviewed 6,100 claims using algorithms and software programs designed to identify improper payments on the face of the claim. The Recovery Auditors found that 5,600 claims were improper and the remaining 500 had no findings. The chart below provides a breakdown of the improper payments identified.

Reason for Improper Payment	Percentage of Improper Claims
Inappropriate billing of spring powered device. (More than 1 spring-powered device for lancets is not considered medically necessary according to CMS policy.)	98%
Inappropriate billing of DME while beneficiary was in an inpatient setting	1.2%
Services billed after a beneficiary's verified date of death	.8%

18. What dates did the sample of 6,100 claims cover?

Answer: These claims had dates of service from January 2008 to February 2013.

19. Is this auditing activity by the Recovery Auditor on an ongoing basis? If not, when was this particular audit performed?

Answer: This audit activity was conducted as part of the Recovery Auditors ongoing efforts to identify improper payments.

20. What methodology, in general, does the Recovery Auditor takes use to select sample claims??

Answer: All new issues for potential audits are approved by CMS before the Recovery Auditors begin widespread review. This ensures that policy and coverage staff approves the audit methodology used by the Recovery Auditors and that the correct interpretation of CMS policies is used in the audits. Once CMS approves the issue for review, the Recovery Auditor will deploy specific algorithms to identify potentially improper claims. The algorithms are based on CMS billing policy and are developed from trending, data mining, data analysis through analytical software, and CMS Regulation and Government Agency Reports such as the Office of Inspector General and General Accounting Office reports.

21. What methodology did the Recovery Auditor use to select the claims from U.S. Healthcare Supply?

Answer: Please see the response to the previous question. The Recovery Auditor reviews claims based on a specific issue, such as billing for supplies after a beneficiary's death, rather than by a specific provider. These claims were selected for review because of the approved issue rather than the Recovery Auditor reviewing claims only for this particular provider. The Recovery Auditors choose which issues to review and issues are approved regionally by Recovery Auditor.

22. Did the sample of 6,100 claims cover a nationwide distribution of claims? If not, which regions were targeted and why?

Answer: Claims were identified for approved issues in:

- Recovery Audit Region C (WV, VA, NC, SC, TN, GA, AL, MS, FL, AR, LA, TX, OK, NM, CO), and
- Recovery Auditor Region D (MO, IA, ND, SD, NE, KS, WY, MT, ID, UT, AZ, NV, CA OR, WA, AK, HI).

The Recovery Auditors choose which issues to review and issues are approved regionally by Recovery Auditor. Therefore, one Recovery Auditor may be reviewing an issue that is not being reviewed in another region.

23. Did CMS make these findings known to U.S. Healthcare? If so, when and how? If not, why not?

Answer: Demand letters related to these claims were issued by CMS' Medicare Administrative Contractors (MACs) to this supplier from December 2010 to April 2013. After an improper payment is identified, the Recovery Auditor sends this information to the MACs for collection in the case of an overpayment or repayment in the case of an underpayment. In the case of an overpayment, the MACs issued a demand letter to the provider which includes the rationale for the determination and instructs providers on how to pay back the overpayment or proceed for additional adjudication or appeal. In addition, providers receive information, in writing or through a claim portal, detailing the reason for the claim denial.

24. What actions has CMS taken regarding the 5,600 improper payments?

Answer: Demand letters related to these claims were issued by the MACs to this supplier from December 2010 to April 2013. The recoupment of an overpayment may be offset against future payments. The MACs have recouped over $75,000 through this offset method and are continuing to offset future claims.

25. Does the $100,635 in overpayments that the Recovery Auditor has demanded from U.S. Healthcare reflect all or only part of the 5,600 improper payments?

Answer: The $100,635 reflects all of the claims that have been identified by the Recovery Auditor as improper and demanded for repayment from the supplier.

26. When did the Recovery Auditor demand the $100,635 in overpayments from U.S. Healthcare?

Answer: Demand letters related to these claims were issued by the Medicare Administrative Contractors to this supplier from December 2010 to April 2013.

27. What response, if any, has the Recovery Auditor received from U.S. Healthcare regarding the $100,635 in overpayments?

Answer: Collection efforts for overpayments and repayments of underpayments are handled by the MACs and not by Recovery Auditors. The recoupment of an overpayment may be offset against future payments. The MACs have recouped more than $75,000 through the offset of future payments made to this supplier, and recoupment through the offset of future claims continues today.

In CMS' April 10, 2013, response to Subcommittee Request for Information, CMS stated that the Recovery Auditor has reviewed more than 590 claims for Med-Care Diabetic & Medical Supplies, Inc., and that more than 400 of those were found to be improper payments. CMS also stated that the Recovery Auditor has demanded $146,689 in overpayments from this supplier, and that most of the overpayments were a result of billing for supplies after a beneficiary's death or billing for supplies while the beneficiary was in a Skilled Nursing Facility.

28. Please provide the most detailed breakdown of what constitutes an "improper payment" that is available from CMS' record keeping. For example, CMS stated that most of the overpayments were a result of two types of incorrect claims – what percentage of the 590 sampled claims fall under each type of incorrect claim?

Answer: The Recovery Auditors reviewed 590 claims using algorithms and software programs designed to identify improper payments on the face of the claim. The Recovery Auditors found that 400 claims were improper and the remaining 190 had no findings. The chart below provides a breakdown of the improper payments identified.

Reason for Improper Payment	Percentage of Improper Claims
Inappropriate billing of DME while beneficiary was in an inpatient setting	86%
Services billed after a beneficiary's verified date of death	9%
Other	5%

29. What dates did the sample of 590 claims cover?

Answer: These claims had dates of service from November 2007 to January 2013.

30. Is this auditing activity by the Recovery Auditor on an ongoing basis? If not, when was this particular audit performed?

Answer: This audit activity was conducted as part of the Recovery Auditors ongoing efforts to identify improper payments.

31. What methodology did the Recovery Auditor use to select the claims from Med-Care Diabetic & Medical Supplies?

Answer: All new issues for potential audits are approved by CMS before the Recovery Auditors begin widespread review. This ensures that policy and coverage staff approves the audit methodology used by the Recovery Auditors and that the correct interpretation of CMS policies is used in the audits. Once CMS approves the issue for review, the Recovery Auditor will deploy specific algorithms to identify potentially improper claims. The algorithms are based on CMS billing policy and are developed from trending, data mining, data analysis through analytical software, and CMS Regulation and Government Agency Reports such as Office of Inspector General and General Accounting Reports.

32. Was the sample of 590 claims chosen randomly or were certain types of claims targeted? If certain types of claims were targeted, which ones and why?

Answer: Please see above. The Recovery Auditor reviews claims based on a specific issue, such as billing for supplies after a beneficiary's death, rather than by a specific provider. These claims were selected for review because of the approved issue rather than the Recovery Auditor reviewing claims only for this particular provider. The Recovery Auditors choose which issues to review and issues are approved regionally by Recovery Auditor.

33. Did the sample of 590 claims cover a nationwide distribution of claims? If not, which regions were targeted and why?

Answer: Claims were identified for approved issues in:

- Recovery Audit Region A (ME, NH, VT, MA, RI, CT, NY, NJ, PA, DE, MD, DC);
- Recovery Audit Region C (WV, VA, NC, SC, TN, GA, AL, MS, FL, AR, LA, TX, OK, NM, CO); and
- Recovery Auditor Region D (MO, IA, ND, SD, NE, KS, WY, MT, ID, UT, AZ, NV, CA OR, WA, AK, HI.)

The Recovery Auditors choose which issues to review and issues are approved regionally by Recovery Auditor. Therefore, one Recovery Auditor may be reviewing an issue that is not being reviewed in another region.

34. Did CMS make these findings known to Med-Care Diabetic & Medical Supplies? If so, when and how? If not, why not?

Answer: Demand letters for these claims were issued by the Medicare Administrative Contractors to this supplier from April 2010 to April 2013. After an improper payment is identified, the Recovery Auditor sends this information to CMS' Medicare Administrative Contractors (MACs) for collection in the case of an overpayment or repayment in the case of an underpayment. In the case of an overpayment, the MACs issue a demand letter to the supplier which includes the rationale for the determination and instructs providers on how to pay back the overpayment or proceed for additional adjudication or appeal. In addition, suppliers receive information, in writing or through a claim portal, detailing the reason for the claim denial. Demand letters for these claims were issued by the MACs to this supplier from April 2010 to April 2013.

35. What actions has CMS taken regarding the 400 improper payments?

Answer: Demand letters for these claims were issued by the MACs to this supplier from April 2010 to April 2013. The recoupment of an overpayment may be offset against future payments. The MACs have recouped over $44,000 through this offset method and are

continuing to offset future claims.

36. Does the $146,689 in overpayments that the Recovery Auditor has demanded from Med-Care Diabetic & Medical Supplies reflect all or only part of the 400 improper payments?

Answer: The $146,689 reflects all of the claims that have been identified by the Recovery Auditor as improper and demanded for repayment from the provider.

37. When did the Recovery Auditor demand the $146,689 in overpayments from Med-Care Diabetic & Medical Supplies?

Answer: Demand letters for these claims were issued by the MACs to this supplier from April 2010 to April 2013.

38. What response, if any, has the Recovery Auditor received from Med-Care Diabetic & Medical Supplies regarding the $146,689 in overpayments?

Answer: The MACs, not Recovery Auditors, handle collection efforts for overpayments and repayments of underpayments. Overpayments may be recouped by offsetting collections against future payments. The MACs have recouped over $44,000 of the amount by offsets, and are continuing to offset future payments.